

## **PRIOR AUTHORIZATION CRITERIA**

This list is current as of January 21, 2026, and pertains to the following formularies:

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| 2026 Pharmacy Benefit Dimensions Prescription Drug Plan (PDP) Part D<br>5 Tier Formulary |
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Pharmacy Benefit Dimensions requires you (or your physician) to get prior authorization for certain drugs listed on the formularies above. This means that you will need to get approval from us before you fill your prescriptions. If you do not get approval, we may not cover the drug. These drugs are listed with a “PA” in the Requirements/Notes column on the formularies. This document contains the Prior Authorization requirements that are associated with the formularies listed above.

If you have any questions, please contact our Medicare Member Services Department at 1-800-667-5936 or, for TTY 711, October 1<sup>st</sup> – March 31<sup>st</sup>: Monday through Sunday from 8 a.m. to 8 p.m. ET, April 1<sup>st</sup> – September 30<sup>th</sup>: Monday through Friday from 8 a.m. to 8 p.m. ET.

Pharmacy Benefit Dimensions is a subsidiary of Independent Health. Independent Health is a PDP with a Medicare contract. Enrollment in Pharmacy Benefit Dimensions PDP depends on contract renewal between Independent Health and CMS.

The formulary may change at any time. You will receive notice when necessary.

## ACTIMMUNE (interferon gamma-1b)

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### Products Affected

- ACTIMMUNE

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use.   |
| Age Restrictions              |   |
| Prescriber Restrictions       |   |
| Coverage Duration             | 1 year  |
| Other Criteria                | A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# ADEMPAS (riociguat)

## Products Affected

- ADEMPAS ORAL TABLET 0.5 MG, 1 MG, 1.5 MG, 2 MG, 2.5 MG

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Pregnancy, severe hepatic impairment (Child-Pugh class C), creatinine clearance below 15 mL/min or on dialysis, concurrent use with nitrates or nitric oxide donors in any form, concurrent use with phosphodiesterase inhibitors   |
| <b>Required Medical Information</b>  | Diagnosis of covered use confirmed by right heart catheterization, submission of patient's WHO Group classification, mean pulmonary arterial pressure greater than 20 mm Hg at rest, pulmonary arterial wedge pressure less than or equal to 15 mm Hg, creatinine clearance (or serum creatinine, actual body weight, and height to calculate estimated creatinine clearance), and pregnancy status for female patients of childbearing potential. For pulmonary arterial hypertension (PAH, WHO Group 1), documentation of pulmonary vascular resistance (PVR) greater than 2 Woods units, submission of current or previous therapies used to treat the condition (see Other Criteria). For chronic thromboembolic pulmonary hypertension (CTEPH, WHO Group 4), confirmation of PVR greater than 3 Woods units, evidence of chronic pulmonary embolism on computed tomography or ventilation/perfusion (V/Q) scan, and attestation patient has inoperable disease or has persistent or recurrent disease after CTEPH surgery (pulmonary thromboendarterectomy). |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to cardiology and pulmonology  |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                | For initial authorization for PAH (WHO Group 1), the patient must have tried and failed to have an adequate response to or had an intolerance/contraindication to both (1) sildenafil or tadalafil and (2) ambrisentan or bosentan.   |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# ALECENSA (alectinib)

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## Products Affected

- ALECENSA

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of ALK-positive tumor, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to oncology  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# ALUNBRIG (brigatinib)

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## Products Affected

- ALUNBRIG

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Uncontrolled hypertension  |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of ALK-positive tumor, baseline blood pressure reading, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# AQNEURSA (levacetylleucine)

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## Products Affected

- AQNEURSA

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Pregnancy, patients without neurologic manifestations of Neimann-Pick disease type C (NPC)   |
| Required Medical Information  | Diagnosis of covered use, submission of neurological symptoms caused by NPC, submission of pregnancy status for female patients of childbearing potential. |
| Age Restrictions              |  |
| Prescriber Restrictions       | Restricted to neurology  |
| Coverage Duration             | 1 year   |
| Other Criteria                | For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required. |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# ARIKAYCE (amikacin inhalation)

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## Products Affected

- ARIKAYCE

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Non-refractory Mycobacterium avium complex (MAC) lung disease   |
| Required Medical Information  | Diagnosis of covered use, documentation of multi-drug regimen for MAC (e.g., ethambutol, a macrolide, and a rifamycin) tried and failed for at least a 6-month trial period, submission of positive sputum culture result obtained after treatment with multi-drug regimen for MAC. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to infectious diseases and pulmonology   |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | Yes   |

# AUGTYRO (repotrectinib)

## Products Affected

- AUGTYRO

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Coadministration with moderate or strong CYP3A4 inhibitors or inducers or P-glycoprotein inhibitors  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, pregnancy status for female patients of childbearing potential. For non-small cell lung cancer, submission of test confirming tumor is ROS1-positive. For other solid tumors, submission of test confirming tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, attestation patient has progressed following treatment or patient has no satisfactory alternative therapy. |
| <b>Age Restrictions</b>              | 12 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to oncology   |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                |  |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | No   |



# AUSTEDO (deutetrabenazine)

## Products Affected

- AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG                      EXTENDED RELEASE THERAPY PACK 12 & 18 & 24 &
- AUSTEDO XR ORAL TABLET EXTENDED RELEASE 24                      30 MG
- HOUR 12 MG, 18 MG, 24 MG, 30 MG, 36 MG, 42 MG,
- 48 MG, 6 MG
- AUSTEDO XR PATIENT TITRATION ORAL TABLET

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Congenital long QT syndrome or a history of cardiac arrhythmia associated with a prolonged QT interval, coadministration with monoamine oxidase inhibitors, actively suicidal or untreated/undertreated depression, hepatic impairment  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of Child-Pugh score. For treatment of chorea associated with Huntington's disease, submission of current or previous therapies used to treat the condition (see Other Criteria).   |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to neurology and psychiatry  |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                | For initial authorization for treatment of chorea associated with Huntington's disease, the patient must have tried and failed to have an adequate response to or had an intolerance/contraindication to tetrabenazine. For each annual reauthorization for tardive dyskinesia, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required. |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# AUVELITY (dextromethorphan/bupropion)

## Products Affected

- AUVELITY

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Seizure disorder, current or prior diagnosis of bulimia or anorexia nervosa, severe hepatic impairment, severe renal impairment, administration of monoamine oxidase inhibitors within 14 days of initiation |
| <b>Required Medical Information</b>  | Diagnosis of covered use, attestation patient has been screened for and does not have bipolar disorder, submission of current or previous therapies used to treat the condition (see Other Criteria).        |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to psychiatry   |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance to two generic on-formulary antidepressants (e.g., bupropion, SSRI, SNRI).           |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |

## AVMAPKI/FAKZYNJA (avutometinib/defactinib)

### Products Affected

- AVMAPKI FAKZYNJA CO-PACK

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Coadministration with moderate or strong CYP3A inhibitors or inducers, proton pump inhibitors, or H2 receptor antagonists  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of test confirming presence of KRAS mutation, pregnancy status for female patients of childbearing potential, attestation patient has received at least one prior systemic therapy. |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to oncology   |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                |  |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |

# AYVAKIT (avapritinib)

## Products Affected

- AYVAKIT ORAL TABLET 100 MG, 200 MG, 25 MG, 300 MG, 50 MG

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Coadministration with moderate or strong CYP3A inducers or strong CYP3A inhibitors. For advanced or indolent systemic mastocytosis, platelet count below $50 \times 10^9/L$ .  |
| Required Medical Information  | Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For gastrointestinal stromal tumor (GIST), submission of test result confirming presence of PDGFRA exon 18 mutation. For advanced or indolent systemic mastocytosis, submission of platelet count. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to allergy, hematology, immunology, and oncology  |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# BALVERSA (erdafitinib)

## Products Affected

- BALVERSA

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | PD-1/PD-L1 inhibitor-eligible patients who have not received this therapy, coadministration with strong CYP3A4 inducers  |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of susceptible FGFR3 genetic alterations, submission of current or previous therapies used to treat the condition (see Other Criteria), pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                | This drug is not recommended for the treatment of patients who are eligible for and have not received prior PD-1 or PD-L1 inhibitor therapy.   |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# BEMPEDOIC ACID

## Products Affected

- NEXLETOL
- NEXLIZET

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Concomitant pravastatin utilization with doses above 40 mg/day, concomitant simvastatin utilization with doses above 20 mg/day, history of tendon disorders or rupture   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of current or previous therapies used to treat the condition (see Other Criteria).  |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       |  |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For initial authorization, the patient must (1) currently be using a statin (unless contraindicated) plus ezetimibe, or (2) have tried and failed to have an adequate response to or had an intolerance to (a) at least two statins or (b) one statin and ezetimibe. At least one statin previously tried and failed must be a hydrophilic statin. For each annual reauthorization, documentation that the patient remains on previously-used lipid-lowering therapies since the previous approval, unless there is documentation of a new contraindication or intolerance requiring discontinuation of a therapy (or therapies) since the previous approval, is required. |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |

# BENLYSTA (belimumab)

## Products Affected

- BENLYSTA SUBCUTANEOUS

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Severe active central nervous system lupus, patients using other biologic medications or intravenous cyclophosphamide  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of current therapies used to treat the condition (see Other Criteria). For systemic lupus erythematosus, submission of autoantibody-positive test result for anti-nuclear antibodies (ANA) and/or anti-double-stranded DNA (anti-dsDNA).  |
| <b>Age Restrictions</b>              |  |
| <b>Prescriber Restrictions</b>       | Restricted to immunology, nephrology, and rheumatology   |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For initial authorization, the patient must be using standard therapy, defined as at least one of the following: systemic corticosteroids (e.g., prednisone), antimalarials (e.g., hydroxychloroquine), or immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate mofetil). For each annual reauthorization, confirmation patient is still using some form of standard therapy (as defined above), unless contraindicated, is required. |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |

## BESREMI (ropeginterferon alfa-2b-njft)

### Products Affected

- BESREMI

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | History or presence of severe psychiatric disorders (including severe depression or suicidal ideation), history of presence of active serious or untreated autoimmune disease, moderate or severe hepatic impairment (Child-Pugh class B or C), immunosuppressed transplant recipients, severe or unstable cardiovascular disease (e.g., uncontrolled hypertension, NYHA class 2-4 congestive heart failure, serious cardiac arrhythmia, significant coronary artery stenosis, unstable angina), stroke or myocardial infarction within previous 6 months, severe renal impairment (eGFR less than 30 mL/min) |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of eGFR, documentation patient has tried and failed to have an adequate response to or had an intolerance/contraindication to hydroxyurea (HU), pregnancy status for female patients of childbearing potential.  |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to hematology and oncology   |
| <b>Coverage Duration</b>             | If patient is taking HU, initially 12 weeks, then 1 year. If patient is not taking HU, 1 year.  |
| <b>Other Criteria</b>                | For the first reauthorization in patients using HU at the start of therapy, attestation patient has tapered completely off HU by the end of week 12 is required.  |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |



# BEXAROTENE GEL

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## Products Affected

- *bexarotene external*

| PA Criteria                   | Criteria Details                       |
|-------------------------------|--|
| Exclusion Criteria            | Pregnancy                              |
| Required Medical Information  | Diagnosis of covered use.              |
| Age Restrictions              | 18 years of age or older               |
| Prescriber Restrictions       | Restricted to dermatology and oncology |
| Coverage Duration             | 1 year                                 |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.          |
| Off Label Uses                |  |
| Part B Prerequisite           | No                                     |
| Prerequisite Therapy Required | No                                     |

# BIOLOGIC RESPONSE MODIFIERS

## Products Affected

- KINERET SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- OTEZLA ORAL TABLET 30 MG
- OTEZLA ORAL TABLET THERAPY PACK 10 & 20 & 30 MG
- SOTYKTU
- STELARA SUBCUTANEOUS SOLUTION 45 MG/0.5ML SYRINGE
- STELARA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- *tyenne subcutaneous*
- *ustekinumab subcutaneous*
- VELSIPITY

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, submission of current or previous therapies used to treat the condition (see Other Criteria). For all drugs managed by this policy except Otezla and Velsipity, submission of baseline latent tuberculosis screening test (Mantoux tuberculin skin test [a.k.a. PPD test] or interferon-gamma release assay [IGRA]).  |
| Age Restrictions              |   |
| Prescriber Restrictions       |   |
| Coverage Duration             | 1 year  |
| Other Criteria                | For initial authorization of a drug managed by this policy, the patient must have tried and failed to have an adequate response to or had an intolerance to at least two preferred agents (an adalimumab biosimilar, Cosentyx, Enbrel, Rinvoq, Skyrizi, an ustekinumab biosimilar, and Xeljanz/Xeljanz XR) for the indication submitted, where possible. For all drugs managed by this policy except Otezla and Velsipity, if TB screening test returns a positive result, coverage will be delayed until latent TB is treated. For each annual reauthorization, yearly TB screening test or chest X-ray required for patients who live in, work in, or travel to areas where TB exposure is likely while on treatment or for those who have previously had a positive TB screening test. |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | Yes   |

# BOSULIF (bosutinib)

## Products Affected

- BOSULIF ORAL CAPSULE 100 MG, 50 MG
- BOSULIF ORAL TABLET

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Coadministration with moderate or strong CYP3A inhibitors or strong CYP3A inducers   |
| Required Medical Information  | Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For accelerated or blast phase Ph+ CML, submission of current or previous therapies used to treat the condition (see Other Criteria).  |
| Age Restrictions              |  |
| Prescriber Restrictions       | Restricted to hematology and oncology  |
| Coverage Duration             | 1 year   |
| Other Criteria                | For initial authorization for accelerated or blast phase Ph+ CML, the patient must have either (1) tried and had an intolerance to dasatinib, imatinib, or nilotinib or (2) resistance to imatinib, defined as (a) failure to achieve or maintain any hematologic improvement within 4 weeks while on imatinib, or (b) failure to achieve a complete hematologic response by 3 months, cytogenetic response by 6 months or major cytogenetic response by 12 months, or (c) progression of disease after a previous cytogenetic or hematologic response, or (d) presence of a genetic mutation in the BCR-ABL gene associated with imatinib resistance. |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |

# BRAFTOVI/MEKTOVI (encorafenib/binimetinib)

## Products Affected

- BRAFTOVI ORAL CAPSULE 75 MG
- MEKTOVI

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of BRAF V600E (or V600K mutation for a melanoma diagnosis, pregnancy status for female patients of childbearing potential. For metastatic melanoma or metastatic non-small cell lung cancer, confirmation that encorafenib and binimetinib will be co-administered. For metastatic colorectal cancer, confirmation that encorafenib and cetuximab will be co-administered. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to oncology  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# BRUKINSA (zanubrutinib)

## Products Affected

- BRUKINSA

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Coadministration with strong CYP3A inducers  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For follicular lymphoma, submission of at least two prior systemic regimens tried and failed and attestation medication will be coadministered with obinutuzumab. For mantle cell lymphoma, submission of prior systemic regimen(s) used. For marginal zone lymphoma, documentation patient has tried and failed at least one anti-CD20-based regimen. |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to hematology and oncology  |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                |  |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |

# BUTALBITAL-CONTAINING PRODUCTS IN OLDER PATIENTS

## Products Affected

- ASCOMP-CODEINE
- *butalbital-acetaminophen oral tablet 50-325 mg*
- *butalbital-apap-caff-cod*
- *butalbital-apap-caffeine oral capsule*
- *butalbital-apap-caffeine oral tablet 50-325-40 mg*
- *butalbital-asa-caff-codeine*
- *butalbital-aspirin-caffeine oral capsule*
- TENCON ORAL TABLET 50-325 MG

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use, documentation patient has tried and failed a preferred alternative such as ibuprofen or rizatriptan, or has contraindications to all alternatives. |
| Age Restrictions              | PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger.   |
| Prescriber Restrictions       |  |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |

## BYLVAY (odevixibat)

### Products Affected

- BYLVAY

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Clinical evidence of decompensated cirrhosis   |
| <b>Required Medical Information</b>  | Diagnosis of covered use confirmed by molecular genetic testing, documentation of cholestasis, defined as one of the following: (1) total serum bile acid greater than the age-adjusted upper limit of normal (ULN), or (2) increased conjugated bilirubin levels, or (3) gamma-glutamyl transferase greater than the age-adjusted ULN, or (4) fat-soluble vitamin deficiency or intractable pruritus explainable only by liver disease, attestation drug-induced pruritus has been ruled out, submission of current or previous therapies used to treat the condition (see Other Criteria). |
| <b>Age Restrictions</b>              |  |
| <b>Prescriber Restrictions</b>       | Restricted to gastroenterology and hepatology  |
| <b>Coverage Duration</b>             | Initially 6 months, then 1 year  |
| <b>Other Criteria</b>                | For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance to at least two of the following: cholestyramine, naltrexone, rifampin, ursodiol. For the first reauthorization, attestation of improvement in pruritus symptoms and submission of liver function testing, including serum bilirubin, since the initial authorization is required. For each annual reauthorization, documented maintenance of a clinical benefit and submission of liver function testing, including serum bilirubin, is required.                   |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |

# CABLIVI (caplacizumab-yhdp)

## Products Affected

- CABLIVI

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use, confirmation drug will be given with plasma exchange and immunosuppressive therapy. If the coverage determination request is not for the patient's first use of caplacizumab, submission of previous aTTP recurrences while on caplacizumab. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to cardiology, hematology, and immunology   |
| Coverage Duration             | 3 months   |
| Other Criteria                | If the coverage determination request is not for the patient's first use of caplacizumab, coverage will not be authorized if the patient has had more than 2 recurrences of aTTP while on therapy.   |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |



# CABOMETYX (cabozantinib)

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## Products Affected

- CABOMETYX

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Severe hepatic impairment, uncontrolled hypertension   |
| Required Medical Information  | Diagnosis of covered use, submission of baseline blood pressure reading, pregnancy status for female patients of childbearing potential. For hepatocellular carcinoma, confirmation patient was previously treated with sorafenib. For differentiated thyroid cancer, attestation patient is radioactive iodine-refractory or ineligible and submission of previous therapy or therapies tried and failed, which must include a VEGFR-targeted therapy at minimum. |
| Age Restrictions              | 12 years of age or older   |
| Prescriber Restrictions       | Restricted to oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |

# CALQUENCE (acalabrutinib)

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## Products Affected

- CALQUENCE ORAL TABLET

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Severe hepatic impairment, coadministration with strong CYP3A inhibitors                                |
| Required Medical Information  | Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to hematology and oncology   |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# CAMZYOS (mavacamten)

## Products Affected

- CAMZYOS

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Left ventricular ejection fraction (LVEF) less than 55%, coadministration with strong CYP2C19 inhibitors, moderate or strong CYP2C19 inducers, moderate or strong CYP3A4 inducers, a non-dihydropyridine (DHP) calcium channel blocker (CCB) plus a beta-blocker, disopyramide, or ranolazine   |
| <b>Required Medical Information</b>  | Diagnosis of covered use including all three of the following: (1) attestation patient has exertional symptoms consistent with the definition of NYHA class II or III disease, (2) confirmation of left ventricular (LV) outflow tract obstruction gradient of at least 50 mm Hg either at rest, during Valsalva maneuver testing, or after exercise, and (3) confirmation of LV wall thickness of at least 15 mm or at least 13 mm if condition is familial, submission of current LVEF, current or previous therapies used to treat the condition (see Other Criteria), pregnancy status for female patients of childbearing potential. |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to cardiology  |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                | For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance/contraindication to both a beta-blocker and a non-DHP CCB. For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.   |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# CAPRELSA (vandetanib)

## Products Affected

- CAPRELSA

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | History of congenital long QT syndrome, torsades de pointes, uncompensated heart failure, or bradyarrhythmias, QTcF interval greater than 450 msec, hypocalcemia, hypokalemia, hypomagnesemia, coadministration with strong CYP3A4 inducers  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of baseline serum potassium, calcium, magnesium, creatinine clearance (or serum creatinine, actual body weight, and height to calculate estimated creatinine clearance), ECG (or QT/QTcF interval), and pregnancy status for female patients of childbearing potential. |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to oncology   |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                |  |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | No   |

# CARGLUMIC ACID

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## Products Affected

- *carglumic acid oral tablet soluble*

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, submission of elevated plasma ammonia level.                                      |
| Age Restrictions              |   |
| Prescriber Restrictions       |   |
| Coverage Duration             | 1 year  |
| Other Criteria                | For each annual reauthorization, updated plasma ammonia level since the previous authorization is required. |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# CERDELGA (eliglustat)

## Products Affected

- CERDELGA

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Ultrarapid CYP2D6 metabolizers, pre-existing cardiac disease, moderate or severe hepatic impairment, long QT syndrome, coadministration with Class Ia or Class III antiarrhythmics. In patients who are poor or intermediate CYP2D6 metabolizers only, mild hepatic impairment. |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of CYP2D6 metabolizer status as detected by a test for determining CYP2D6 genotype, liver function testing or Child-Pugh score.  |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       |   |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                | For each annual reauthorization, updated liver function testing or Child-Pugh score since the previous authorization is required.   |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |

# CFTR MODULATOR THERAPIES

## Products Affected

- KALYDECO
- ORKAMBI
- SYMDEKO
- TRIKAFTA ORAL TABLET THERAPY PACK 100-50-75 & 150 MG, 50-25-37.5 & 75 MG
- TRIKAFTA ORAL THERAPY PACK

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Coadministration with strong CYP3A inducers. For Trikafta, severe hepatic impairment.  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of cystic fibrosis (CF) mutation test confirming presence of CFTR gene mutations as indicated (see Other Criteria).   |
| <b>Age Restrictions</b>              |  |
| <b>Prescriber Restrictions</b>       | Restricted to pulmonology  |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | Initial authorization requires CF mutation test confirming presence of CFTR gene mutations as follows, by drug being requested: (a) for Kalydeco, a mutation predicted to be responsive to ivacaftor based on section 12.1 of the prescribing information, (b) for Orkambi, two copies of the F508del mutation, (c) for Symdeko, two copies of the F508del mutation or at least one mutation predicted to be responsive based on section 12.1 of the prescribing information, (d) for Trikafta, at least one mutation predicted to be responsive based on section 12.1 of the prescribing information or a responsive mutation based on in vitro data. |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | No   |

# CGRP INHIBITORS

## Products Affected

- AIMOVIG SUBCUTANEOUS SOLUTION AUTO-INJECTOR 140 MG/ML, 70 MG/ML
- EMGALITY
- EMGALITY (300 MG DOSE)
- NURTEC
- QULIPTA
- UBRELVY

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            |  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of current or previous therapies used to treat the condition (see Other Criteria). For migraine prevention, submission of baseline headache days per month from medical chart.  |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       |  |
| <b>Coverage Duration</b>             | For migraine headache prevention, initially 3 months, then 1 year. For acute migraine, 1 year.   |
| <b>Other Criteria</b>                | For initial authorization for acute migraine treatment, the patient must have tried and failed to have an adequate response to one triptan or have a documented contraindication to triptan use. For initial authorization for episodic migraine prevention, the patient must have documentation of fewer than 15 headache days per month. For initial authorization of Emgality for migraine prevention, the patient must have tried and failed to have an adequate response to or had an intolerance to Aimovig. For the first reauthorization for migraine prevention, submission of on-treatment headache days per month demonstrating improvement from baseline is required. For each annual reauthorization for migraine prevention, documented maintenance of a clinical benefit is required. |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |



# CHENODAL (chenodiol)

## Products Affected

- CHENODAL

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Pregnancy, known hepatocyte dysfunction, bile duct abnormalities such as intrahepatic cholestasis, primary biliary cirrhosis, or sclerosing cholangitis, radiopaque stones, nonvisualizing gallbladder confirmed as nonvisualizing after 2 consecutive single doses of dye, compelling reasons for gallbladder surgery |
| <b>Required Medical Information</b>  | Diagnosis of covered use.  |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to gastroenterology and hepatology  |
| <b>Coverage Duration</b>             | 24 months  |
| <b>Other Criteria</b>                | Safety beyond 24 months is not established and will not be authorized.   |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | No   |

## CHOLBAM (cholic acid)

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### Products Affected

- CHOLBAM

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use, submission of liver function testing.  |
| Age Restrictions              |  |
| Prescriber Restrictions       | Restricted to gastroenterology, hepatology, and pediatric gastroenterology   |
| Coverage Duration             | Initially 3 months, then 1 year  |
| Other Criteria                | For the first reauthorization, documentation of liver function improvement without complete biliary obstruction or persistent clinical or laboratory indications of worsening liver function or cholestasis is required. For each annual reauthorization, updated liver function testing since the previous authorization is required. |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# COMETRIQ (cabozantinib)

## Products Affected

- COMETRIQ (100 MG DAILY DOSE) ORAL KIT 80 & 20 MG
- COMETRIQ (140 MG DAILY DOSE) ORAL KIT 3 X 20 MG & 80 MG
- COMETRIQ (60 MG DAILY DOSE)

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Severe hepatic impairment (Child-Pugh class C), uncontrolled hypertension  |
| Required Medical Information  | Diagnosis of covered use, submission of baseline blood pressure reading, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# COPIKTRA (duvelisib)

## Products Affected

- COPIKTRA ORAL CAPSULE 15 MG, 25 MG

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Request as first- or second-line therapy, coadministration with strong CYP3A inducers  |
| Required Medical Information  | Diagnosis of covered use, submission of at least two prior systemic therapies tried and failed, submission of pregnancy status for female patients of childbearing potential, attestation patient will receive prophylaxis for <i>Pneumocystis jirovecii</i> pneumonia (PJP) and, if necessary, cytomegalovirus. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to hematology and oncology  |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# CORTICOTROPIN

## Products Affected

- CORTROPHIN
- CORTROPHIN GEL

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Request for IV administration, patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, a history of or presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction, or sensitivity to proteins of porcine origin  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of blood pressure reading and baseline serum sodium and potassium levels.  |
| <b>Age Restrictions</b>              |   |
| <b>Prescriber Restrictions</b>       |   |
| <b>Coverage Duration</b>             | 3 weeks   |
| <b>Other Criteria</b>                | For each reauthorization, updated blood pressure, sodium, and potassium levels since the previous authorization are required. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |

# COTELLIC/ZELBORAF (cobimetinib/vemurafenib)

## Products Affected

- COTELLIC
- ZELBORAF

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | For cobimetinib, coadministration with moderate or strong CYP3A inhibitors or inducers. For vemurafenib, electrolyte abnormalities that are not correctable, long QT syndrome, coadministration with drugs that prolong the QT interval.  |
| <b>Required Medical Information</b>  | Diagnosis of covered use including verification of BRAF V600 mutation as needed for diagnosis, submission of pregnancy status for female patients of childbearing potential. For patients using cobimetinib, submission of left ventricular ejection fraction (LVEF) with a requirement the baseline LVEF is greater than or equal to 50%. For patients using vemurafenib, submission of QTc interval with a requirement the QT interval is less than or equal to 500 msec. |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to oncology  |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                |   |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |

## CRESEMBA (isavuconazonium)

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### Products Affected

- CRESEMBA ORAL CAPSULE 186 MG

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Familial short QT syndrome, coadministration with strong CYP3A inhibitors or inducers |
| Required Medical Information  | Diagnosis of covered use.   |
| Age Restrictions              | 6 years of age or older   |
| Prescriber Restrictions       | Restricted to hematology, infectious diseases, and oncology                           |
| Coverage Duration             | 6 months  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# CYSTEAMINE EYE DROPS

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## Products Affected

- CYSTADROPS
- CYSTARAN

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, confirmation of corneal cysteine crystal deposits as seen on slit-lamp examination. |
| Age Restrictions              |   |
| Prescriber Restrictions       | Restricted to metabolic diseases specialty, ophthalmology, and optometry                                      |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |



# DALFAMPRIDINE

## Products Affected

- *dalfampridine er*

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | History of seizure, moderate or severe renal impairment (CrCl less than or equal to 50 mL/min)   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of creatinine clearance (or serum creatinine, actual body weight, and height to calculate estimated creatinine clearance), confirmation that patient is able to walk. |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to neurology  |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For each annual reauthorization, updated creatinine clearance since the previous authorization and confirmation patient is able to walk is required.   |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | No   |

# DASATINIB

## Products Affected

- dasatinib oral tablet 100 mg, 140 mg, 20 mg, 50 mg, 70 mg, 80 mg

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Uncorrected hypokalemia or hypomagnesemia, coadministration with proton pump inhibitors or H2 receptor antagonists   |
| Required Medical Information  | Diagnosis of covered use, submission of serum potassium and magnesium, pregnancy status for female patients of childbearing potential. For adults with resistance or intolerance to prior therapy, documentation of prior therapy. |
| Age Restrictions              |  |
| Prescriber Restrictions       | Restricted to hematology and oncology  |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# DAURISMO (glasdegib)

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## Products Affected

- DAURISMO ORAL TABLET 100 MG, 25 MG

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Coadministration with strong CYP3A inducers  |
| Required Medical Information  | Diagnosis of covered use, confirmation patient will also be receiving cytarabine as part of chemotherapeutic regimen. If patient is under 75 years of age, documentation of comorbidities that preclude use of intensive induction chemotherapy, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to hematology and oncology  |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# DEFERASIROX

## Products Affected

- *deferasirox oral tablet soluble*

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Severe hepatic impairment, estimated glomerular filtration rate (eGFR) less than 40 mL/min, platelet count below $50 \times 10^9/L$ , high-risk myelodysplastic syndromes, advanced malignancies |
| Required Medical Information  | Diagnosis of covered use, submission of complete blood count (CBC), liver function testing (LFT), ferritin, and eGFR from the previous 3 months.   |
| Age Restrictions              |  |
| Prescriber Restrictions       |  |
| Coverage Duration             | 3 months   |
| Other Criteria                | For each reauthorization, updated ferritin level and platelet count drawn within last 3 months and updated CBC, LFT, and eGFR drawn within the previous 6 months is required.                    |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# DEFERIPRONE

## Products Affected

- *deferiprone*

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Absolute neutrophil count (ANC) below $1.5 \times 10^9/L$ , transfusional iron overload in myelodysplastic syndrome or Diamond Blackfan anemia |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of serum ferritin levels, ANC, pregnancy status for female patients of childbearing potential.            |
| <b>Age Restrictions</b>              |  |
| <b>Prescriber Restrictions</b>       |  |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For each annual reauthorization, updated ferritin level and ANC within last 3 months is required.  |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | No   |

# DIACOMIT (stiripentol)

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## Products Affected

- DIACOMIT

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Requests for monotherapy, moderate or severe renal impairment, moderate or severe hepatic impairment |
| Required Medical Information  | Diagnosis of covered use, confirmation patient is also receiving clobazam.                           |
| Age Restrictions              |  |
| Prescriber Restrictions       | Restricted to neurology  |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# DICHLORPHENAMIDE

## Products Affected

- *dichlorphenamide*
- *ormalvi*

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Concomitant use of high dose aspirin, severe pulmonary disease limiting compensation to metabolic acidosis, hepatic insufficiency                   |
| <b>Required Medical Information</b>  | Diagnosis of covered use.   |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       |   |
| <b>Coverage Duration</b>             | Initially 2 months, then 1 year   |
| <b>Other Criteria</b>                | For each reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required. |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |

# DICLOFENAC PATCH

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## Products Affected

- *diclofenac epolamine external*

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery, use on non-intact or damaged skin resulting from any etiology including exudative dermatitis, eczema, infection lesions, burns, or wounds, pregnancy after 30 weeks gestation |
| Required Medical Information  | Diagnosis of acute pain, defined as short-term pain not lasting longer than a 3-month period.   |
| Age Restrictions              |   |
| Prescriber Restrictions       |   |
| Coverage Duration             | 3 months  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |



# DIGOXIN IN OLDER PATIENTS

## Products Affected

- *digoxin oral tablet 250 mcg*

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use. Patient must have tried and failed to respond adequately to 0.125 mg of digoxin.  |
| Age Restrictions              | PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger.  |
| Prescriber Restrictions       | PA not required for cardiology  |
| Coverage Duration             | 1 year  |
| Other Criteria                | PA not required for doses less than or equal to 0.125 mg per day. For each annual reauthorization, provider must attest patient is undergoing required laboratory testing to monitor kidney function and electrolytes and patient is not experiencing signs or symptoms of digoxin toxicity related to drug administration. |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | Yes   |

# DOPTELET (avatrombopag)

## Products Affected

- DOPTELET ORAL TABLET 20 MG

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Normalization of platelet counts before a procedure in patients with chronic liver disease  |
| <b>Required Medical Information</b>  | Diagnosis of covered use. For thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure, submission of platelet count with a requirement it is less than $50 \times 10^9/L$ . For immune thrombocytopenia (ITP), submission of platelet count with a requirement it is less than $30 \times 10^9/L$ or less than $50 \times 10^9/L$ with symptomatic bleeding, documentation patient has undergone splenectomy. If the patient has not undergone splenectomy, submission of current or previous therapies used to treat the condition (see Other Criteria).                    |
| <b>Age Restrictions</b>              |   |
| <b>Prescriber Restrictions</b>       | Restricted to gastroenterology, hematology, hepatology, and surgery   |
| <b>Coverage Duration</b>             | For patients undergoing a procedure, 5 days. For ITP, initially 2 months, then 1 year.  |
| <b>Other Criteria</b>                | For initial authorization for ITP, the patient must have tried and failed to have an adequate response to or had an intolerance to at least two ITP therapies from different classes including systemic corticosteroids, immunoglobulins, danazol, fostamatinib, or cytotoxics/immunosuppressants such as rituximab. For first reauthorization for ITP, documentation of an improvement in platelet count greater than or equal to $50 \times 10^9/L$ after at least 4 weeks on the maximum tolerated dose is required. For each annual reauthorization, documented maintenance of this clinical benefit is required. |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# DRONABINOL

## Products Affected

- *dronabinol*

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use. If authorization is requested for treatment of nausea and vomiting associated with cancer therapy, submission of current or previous therapies used to treat the condition (see Other Criteria).   |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       |  |
| Coverage Duration             | 1 year   |
| Other Criteria                | For initial authorization for treatment of nausea and vomiting associated with cancer therapy, the patient must have tried and failed to have an adequate response to or had an intolerance to at least one 5-HT3 receptor antagonist (e.g., granisetron, ondansetron). If the medication is being administered related to cancer treatment and is a full replacement for intravenous administration of antiemetic therapy within 48 hours of cancer treatment, it is covered as a Part B benefit. To be eligible for Part B coverage, the prescribing physician must indicate this on the prescription. |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |

# DUPIXENT (dupilumab)

## Products Affected

- DUPIXENT SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- DUPIXENT SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 200 MG/1.14ML, 300 MG/2ML

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | Diagnosis of covered use. For atopic dermatitis (AD), asthma, COPD, chronic rhinosinusitis with nasal polyps (CRSwNP), and prurigo nodularis (PN), submission of current and previous therapies used to treat the condition (see Other Criteria). For AD, documentation of at least 10% body surface area involvement. For asthma, (1) documentation patient has a pre-bronchodilator FEV1 less than 80% predicted or less than 90% in children, and (2) submission of either (a) blood eosinophil (eos) count of at least 150 cells/mcL obtained within 6 weeks of therapy initiation, or (b) documentation asthma requires daily oral corticosteroid for control. For COPD, (1) documentation patient has a post-bronchodilator FEV1/FVC ratio less than 0.7 and a post-bronchodilator FEV1 30% to 80% predicted, (2) submission of blood eos count of at least 300 cells/mcL obtained within 6 weeks of therapy initiation, and (3) documentation patient is symptomatic (see Other Criteria). For CRSwNP, (1) documentation of evidence of nasal polyps, and (2) attestation that patient has symptomatic nasal congestion. For eosinophilic esophagitis, (1) documentation of upper endoscopy with biopsy showing at least 15 eos/high-power field or 60 eos/mm2, and (2) documentation of signs/symptoms, including but not limited to trouble swallowing, food sticking in esophagus, acid reflux, abdominal or chest pain, or nausea and vomiting. For PN, (1) documentation of pruritus lasting at least 6 weeks, and (2) documentation of presence of pruriginous firm, nodular lesions. |
| Age Restrictions             |  |
| Prescriber Restrictions      | Restricted to allergy, dermatology, gastroenterology, immunology, otolaryngology/otorhinolaryngology, and pulmonology  |
| Coverage Duration            | Initially 6 months, then 1 year  |

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Other Criteria                | <p>For initial authorization for AD or PN, the patient must have tried and failed to have an adequate response to at least a moderate strength topical corticosteroid for at least four weeks, have a contraindication to topical corticosteroids, or documentation must be submitted as to why this therapy is not advisable. For initial authorization for asthma, patient must be on a drug regimen as recommended by GINA guidelines prior to the use of biologic medications, consisting of, at a minimum, a maximally-tolerated dose of inhaled corticosteroid (ICS), a long-acting beta-agonist (LABA), and a long-acting antimuscarinic antagonist (LAMA), and the provider must attest this therapy will be continued after starting dupilumab. For initial authorization for COPD, patient must (1) be on stable doses of standard-of-care COPD medications including an ICS, a LABA, and a LAMA, unless contraindicated, for at least 90 days prior to starting dupilumab, and provider must attest this therapy will be continued after starting dupilumab, and (2) meet at least one of the following definitions of having symptomatic COPD: (a) modified Medical Research Council (mMRC) dyspnea scale score of greater than or equal to 2, or (b) COPD Assessment Test (CAT) score of at least 10. For initial authorization for CRSwNP, patient must have tried an intranasal corticosteroid for at least two months (and provider must attest this will be continued after starting dupilumab), have a contraindication to intranasal corticosteroids, or documentation must be submitted as to why this therapy is not advisable. For each reauthorization for asthma or COPD, confirmation patient is still using triple ICS-LABA-LAMA inhaler therapy, unless contraindicated, and documentation of a clinical benefit (e.g., reduction from baseline in rate of annual exacerbations or severe exacerbations, systemic corticosteroid dose, or disease symptom score, improvement in FEV1) or maintenance of a benefit previously achieved is required. For each reauthorization for CRSwNP, confirmation patient is still using an intranasal corticosteroid, unless contraindicated, and documentation of a clinical benefit (e.g., reduction from baseline in nasal congestion, nasal polyp score or systemic corticosteroid dose) or maintenance of a benefit previously achieved is required. For each reauthorization for AD or PN, documentation of a clinical benefit (e.g., reduction from baseline in itch severity, hive count, or proportion of body affected by condition) or maintenance of a benefit previously achieved is required. For each reauthorization for eosinophilic esophagitis, documentation of a clinical benefit (e.g., histological remission, reduction from baseline in dysphagia) or maintenance of a benefit previously achieved is required.</p> |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | Yes   |

# ELTROMBOPAG

## Products Affected

- *eltrombopag olamine oral packet*
- *eltrombopag olamine oral tablet 12.5 mg, 25 mg, 50 mg, 75 mg*

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            |   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of platelet count (see Other Criteria). For immune thrombocytopenia (ITP), submission of previous therapies tried and failed (see Other Criteria). For thrombocytopenia in patients with chronic hepatitis C, attestation patient will be receiving interferon therapy to treat HCV. For aplastic anemia (AA), submission of immunosuppressive therapy that will be used concomitantly or, in the case of refractory disease, submission of therapies tried and failed.  |
| <b>Age Restrictions</b>              |   |
| <b>Prescriber Restrictions</b>       | Restricted to gastroenterology, hematology, hepatology, and infectious diseases   |
| <b>Coverage Duration</b>             | For ITP, initially 12 weeks, then 1 year. For AA, 6 months. For all other indications, 1 year.  |
| <b>Other Criteria</b>                | For initial authorization for ITP, submission of (1) platelet count less than $30 \times 10^9/L$ or less than $50 \times 10^9/L$ with documented increased risk of bleeding and (2) documentation patient has undergone splenectomy or tried and failed two different ITP therapies including systemic corticosteroids, immunoglobulins, danazol, fostamatinib, or cytotoxics/immunosuppressants such as rituximab is required. For initial authorization in patients with chronic hepatitis C, submission of platelet count less than $75 \times 10^9/L$ is required. For initial authorization for AA, submission of platelet count less than $30 \times 10^9/L$ is required. For first reauthorization, submission of an updated platelet count showing improvement from baseline is required. For each reauthorization, documented maintenance of a clinical benefit is required. |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# ENSACOVE (ensartinib)

## Products Affected

- ENSACOVE

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Prior ALK-inhibitor use, severe hepatic impairment, coadministration with moderate or strong CYP3A4 inhibitors or inducers or P-glycoprotein inhibitors   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of test confirming presence of ALK-positive tumor, attestation patient has not previously received an ALK-inhibitor, pregnancy status for female patients of childbearing potential. |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to oncology  |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                |   |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |

## EOHILIA (budesonide oral suspension)

### Products Affected

- EOHILIA

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use, documentation of upper endoscopy with biopsy showing at least 15 eosinophils per high-power field or 60 eosinophils/mm <sup>2</sup> , documentation of signs/symptoms, including but not limited to trouble swallowing, food sticking in esophagus, acid reflux, abdominal or chest pain, or nausea and vomiting, documentation patient has tried and failed at least an 8-week course of proton pump inhibitor therapy (i.e., patient has eosinophilic esophagitis unrelated to gastroesophageal reflux). |
| Age Restrictions              | 11 years of age or older   |
| Prescriber Restrictions       | Restricted to allergy, gastroenterology, immunology, and otolaryngology/otorhinolaryngology  |
| Coverage Duration             | 12 weeks   |
| Other Criteria                | A maximum of one 12-week course will be allowed every 365 days.  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |



# EPIDIOLEX (cannabidiol)

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## Products Affected

- EPIDIOLEX

| PA Criteria                   | Criteria Details              |
|-------------------------------|-------------------------------|
| Exclusion Criteria            |                               |
| Required Medical Information  | Diagnosis of covered use.     |
| Age Restrictions              |                               |
| Prescriber Restrictions       | Restricted to neurology       |
| Coverage Duration             | 1 year                        |
| Other Criteria                |                               |
| Indications                   | All FDA-approved Indications. |
| Off Label Uses                |                               |
| Part B Prerequisite           | No                            |
| Prerequisite Therapy Required | No                            |

## ERIVEDGE (vismodegib)

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### Products Affected

- ERIVEDGE

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Pregnancy   |
| Required Medical Information  | Diagnosis of covered use, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to oncology  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# EVEROLIMUS

## Products Affected

- *everolimus oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg*
- *everolimus oral tablet soluble*
- *torpenz*

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Coadministration with dual strong CYP3A4/P-glycoprotein inhibitors   |
| Required Medical Information  | Diagnosis of covered use and submission of pregnancy status for female patients of childbearing potential. For postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer, documentation of treatment failure with letrozole or anastrozole and confirmation drug is being used in combination with exemestane. |
| Age Restrictions              |  |
| Prescriber Restrictions       | Restricted to neurology and oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |

# EVRYSDI (risdiplam)

## Products Affected

- EVRYSDI

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use confirmed by genetic testing including either (a) homozygous deletion of SMN1 exon 7 or (b) compound heterozygosity for SMN1 exon 7 deletion and small mutation, documentation of two or more copies of the SMN2 gene by genetic testing. |
| Age Restrictions              |  |
| Prescriber Restrictions       | Restricted to neurology  |
| Coverage Duration             | Initially 6 months, then 1 year  |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# FABHALTA (iptacopan) EGWP

## Products Affected

- FABHALTA

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Severe hepatic impairment (Child-Pugh class C). For complement 3 glomerulopathy (C3G), recurrent C3G after kidney transplant.   |
| <b>Required Medical Information</b>  | Diagnosis of covered use. For paroxysmal nocturnal hemoglobinuria (PNH), submission of flow cytometry analysis confirming presence of clones of PNH cells, submission of any laboratory result or objective sign attributable to PNH, including but not limited to hemoglobin less than 10 g/dL, lactate dehydrogenase greater than 1.5 times the upper limit of normal, hemosiderinuria, anemia, or unexplained/unusual (e.g., skin, splanchnic vein, cerebral vein) thrombosis, attestation the patient does not have severe hepatic impairment. For the reduction of proteinuria in adults with primary immunoglobulin A nephropathy (IgAN), the diagnosis is confirmed by biopsy or submission of 24-hour urine protein-to-creatinine ratio (UPCR) of at least 1.5 g/g. For C3G, confirmation of diagnosis by kidney biopsy, submission of 24-hour UPCR of at least 1.0 g/g, and submission of current medications being used for condition (see Other Criteria). |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to hematology and nephrology   |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                | PA applies to all. For C3G, the patient must currently be taking a maximally-tolerated ACE inhibitor or ARB plus either a systemic corticosteroid and/or mycophenolate. Continuation of therapy requests require confirmation that the patient has demonstrated a clinical improvement (or maintenance of improvement once achieved) from baseline.   |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# FILSPARI (sparsentan)

## Products Affected

- FILSPARI

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Pregnancy, hepatic impairment, coadministration with renin-angiotensin system antagonists, endothelin receptor antagonists, proton pump inhibitors, or H2-receptor blockers  |
| <b>Required Medical Information</b>  | Diagnosis of primary IgA nephropathy confirmed by biopsy, submission of 24-hour urine protein of at least 0.5 g/day or 24-hour urine protein-to-creatinine ratio (UPCR) of at least 0.8 g/g, eGFR, liver function testing or Child-Pugh score, pregnancy status for female patients of childbearing potential, submission of current or previous therapies used to treat the condition (see Other Criteria).   |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to immunology and nephrology  |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For initial authorization, the patient must be currently using (or have a contraindication to the use of) a maximally-tolerated dose of an ACE inhibitor or ARB and tried and failed to have an adequate response to or had an intolerance to at least one SGLT-2 inhibitor (e.g., dapagliflozin, empagliflozin). For each annual reauthorization, documentation of clinically relevant response to therapy, including either stabilization or improvement of UPCR or a reduction in 24-hour urine protein from baseline, is required. |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |

# FINTEPLA (fenfluramine)

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## Products Affected

- FINTEPLA

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Administration of monoamine oxidase inhibitors within 14 days of initiation |
| Required Medical Information  | Diagnosis of covered use.   |
| Age Restrictions              |   |
| Prescriber Restrictions       | Restricted to neurology   |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# FIRDAPSE (amifampridine)

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## Products Affected

- FIRDAPSE

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | History of seizure   |
| Required Medical Information  | Diagnosis of covered use confirmed by either electromyography or calcium channel antibody testing.   |
| Age Restrictions              | 6 years of age or older  |
| Prescriber Restrictions       | Restricted to neurology  |
| Coverage Duration             | 1 year   |
| Other Criteria                | For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required. |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |



# FOTIVDA (tivozanib)

## Products Affected

- FOTIVDA

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Uncontrolled hypertension, severe hepatic impairment, coadministration with strong CYP3A inducers   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of baseline blood pressure reading, submission of current or previous therapies used to treat the condition (see Other Criteria), liver function testing or Child-Pugh score, pregnancy status for female patients of childbearing potential, confirmation patient has not had episodes of symptomatic heart failure or unstable angina, a myocardial infarction, an arterial thrombotic event, or a significant bleeding event in the 6 months preceding the prior authorization request. |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to oncology  |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                | For initial authorization, the patient must have tried and failed to have an adequate response to a minimum of two previous systemic therapies, including the failure of at least one prior VEGFR inhibitor.  |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# FRUZAQLA (fruquintinib)

## Products Affected

- FRUZAQLA ORAL CAPSULE 1 MG, 5 MG

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Severe hepatic impairment, uncontrolled hypertension, coadministration with strong CYP3A inducers  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of baseline blood pressure reading, submission of current or previous therapies used to treat the condition (see Other Criteria), liver function testing or Child-Pugh score, pregnancy status for female patients of childbearing potential, documentation of any clinically significant cardiovascular disease or thromboembolic events, and, if there is a positive history, prescriber attestation benefit to patient outweighs potential risk of thromboembolic event. |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to oncology   |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For initial authorization, the patient must have documentation of previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type and medically appropriate, an anti-EGFR therapy.   |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |

# GATTEX (teduglutide)

## Products Affected

- GATTEX

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use including confirmation of dependency on parenteral nutrition.   |
| Age Restrictions              |  |
| Prescriber Restrictions       | Restricted to gastroenterology   |
| Coverage Duration             | Initially 6 months, then 1 year  |
| Other Criteria                | For the first reauthorization for adults 18 years of age or older, submission of reduction in weekly parenteral nutrition/intravenous support volume from baseline and documentation that a colonoscopy or alternate imaging of the entire colon and upper GI endoscopy with polyp removal and showing no active gastrointestinal malignancy is required. For each annual reauthorization, documented maintenance of a clinical benefit is required. |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |

# GAVRETO (pralsetinib)

## Products Affected

- GAVRETO

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Coadministration with strong CYP3A4 inhibitors, uncontrolled hypertension   |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of RET gene fusion or mutation, baseline blood pressure reading, pregnancy status for female patients of childbearing potential. For thyroid cancer, attestation patient is radioactive iodine-refractory or ineligible. |
| Age Restrictions              | 12 years of age or older  |
| Prescriber Restrictions       | Restricted to oncology  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# GEFITINIB

## Products Affected

- *gefitinib*

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of EGFR exon 19 deletions or exon 21 (L858R) substitution mutations, submission of pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to oncology  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# GILOTRIF (afatinib)

## Products Affected

- GILOTRIF

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For non-small cell lung cancer, submission of test confirming presence of non-resistant epidermal growth factor receptor mutations. For metastatic squamous non-small cell lung cancer, documentation of progression after platinum-based chemotherapy. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to oncology  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | Yes   |

# GLP-1 AGONISTS

## Products Affected

- MOUNJARO SUBCUTANEOUS SOLUTION AUTO-INJECTOR 10 MG/0.5ML, 12.5 MG/0.5ML, 15 MG/0.5ML, 2.5 MG/0.5ML, 5 MG/0.5ML, 7.5 MG/0.5ML
- OZEMPIC (0.25 OR 0.5 MG/DOSE) SUBCUTANEOUS SOLUTION PEN-INJECTOR 2 MG/3ML
- OZEMPIC (1 MG/DOSE) SUBCUTANEOUS SOLUTION PEN-INJECTOR 4 MG/3ML
- OZEMPIC (2 MG/DOSE)
- RYBELSUS (FORMULATION R2) ORAL TABLET 1.5 MG, 4 MG, 9 MG
- RYBELSUS ORAL TABLET 14 MG, 3 MG, 7 MG
- TRULICITY SUBCUTANEOUS SOLUTION AUTO-INJECTOR

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Off-label use for weight management (see Other Criteria)  |
| Required Medical Information  | Diagnosis of type 2 diabetes confirmed through one of the following: (1) medical record, or (2) ICD-10 on medical claims, or (3) laboratory results (verifying a hemoglobin A1c greater than or equal to 6.5%, a fasting plasma glucose greater than or equal to 126 mg/dL, a 2-hour postprandial blood glucose greater than or equal to 200 mg/dL after an oral glucose tolerance test, or a random plasma blood glucose greater than or equal to 200 mg/dL combined with classic signs/symptoms of hyperglycemia or hyperglycemic crisis), attestation patient is not receiving another GLP-1 agonist for the treatment of any condition. |
| Age Restrictions              | Age must be consistent with the prescribing information of the drug and condition being treated   |
| Prescriber Restrictions       |   |
| Coverage Duration             | 1 year  |
| Other Criteria                | These products will not be approved for weight management as this off-label use is currently excluded from coverage under Medicare Part D.  |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

## GOMEKLI (mirdametinib)

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### Products Affected

- GOMEKLI

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. |
| Age Restrictions              |   |
| Prescriber Restrictions       | Restricted to neurology and oncology  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |



# GROWTH HORMONE

## Products Affected

- NORDITROPIN FLEXPEN SUBCUTANEOUS SOLUTION  
PEN-INJECTOR

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, documentation of growth failure, submission of IGF-1 levels, height, weight, creatinine clearance (or serum creatinine), fasting blood glucose, and bone age if applicable based on patient age and diagnosis.  |
| Age Restrictions              |   |
| Prescriber Restrictions       | Restricted to endocrinology and nephrology  |
| Coverage Duration             | 1 year  |
| Other Criteria                | For each annual reauthorization, submission of updated IGF-1 level, bone age (if applicable based on patient age and diagnosis), height, weight, creatinine clearance (or serum creatinine), fasting glucose, and confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required. |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# HEREDITARY ANGIOEDEMA THERAPIES, ACUTE

## Products Affected

- *icatibant acetate subcutaneous solution prefilled syringe*
- *sajazir subcutaneous solution prefilled syringe*

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Requests for prophylactic hereditary angioedema therapy.            |
| Required Medical Information  | Diagnosis of covered use.   |
| Age Restrictions              | Age must be consistent with the prescribing information of the drug |
| Prescriber Restrictions       | Restricted to allergy, dermatology, hematology, and immunology      |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.                                       |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# HEREDITARY ANGIOEDEMA THERAPIES, MAINTENANCE

## Products Affected

- HAEGARDA
- TAKHZYRO SUBCUTANEOUS SOLUTION
- TAKHZYRO SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 300 MG/2ML

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Requests for acute hereditary angioedema (HAE) therapy (attacks)   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of objective or subjective documentation that prophylactic therapy is medically necessary, including, but not limited to activity of disease and disease burden, the frequency of HAE attacks, and quality of life. |
| <b>Age Restrictions</b>              | Age must be consistent with the prescribing information of the drug  |
| <b>Prescriber Restrictions</b>       | Restricted to allergy, dermatology, hematology, and immunology   |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                |  |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | No   |

# HERNEXEOS (zongertinib)

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## Products Affected

- HERNEXEOS

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use including documentation the tumor is nonsquamous, submission of test confirming tumor is HER2-positive, pregnancy status for female patients of childbearing potential, documentation of at least one previous systemic therapy that was tried and failed. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to oncology  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | Yes   |

# IBRANCE (palbociclib)

## Products Affected

- IBRANCE

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Coadministration with strong CYP3A4 inducers   |
| Required Medical Information  | Diagnosis of covered use, submission of genetic tumor testing confirming primary tumor type is HR-positive, HER2-negative, attestation the treatment regimen will include concomitant use of an aromatase inhibitor or fulvestrant, pregnancy status for female patients of childbearing potential. For endocrine-resistant breast cancer, submission of genetic tumor testing confirming primary tumor type is PIK3CA-mutated, attestation patient will be taking palbociclib concurrently with inavolisib. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# IBTROZI (taletrectinib)

## Products Affected

- IBTROZI

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Coadministration with moderate or strong CYP3A inhibitors or inducers, proton pump inhibitors, or H2 receptor antagonists   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of test confirming tumor is ROS1-positive, pregnancy status for female patients of childbearing potential, submission of current or previous therapies used to treat the condition (see Other Criteria). |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to oncology  |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                | For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance to either crizotinib or entrectinib or have contraindications to both crizotinib and entrectinib.                     |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# ICLUSIG (ponatinib)

## Products Affected

- ICLUSIG

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Newly diagnosed chronic phase chronic myeloid leukemia (CP-CML), uncontrolled hypertension  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, documentation of T315I mutation status (present or absent), submission of baseline blood pressure reading, pregnancy status for female patients of childbearing potential. For newly-diagnosed Ph+ acute lymphoblastic leukemia (ALL), attestation drug will be used with chemotherapy. For CP-CML that is not T315I-positive, documentation of resistance or intolerance to at least two prior kinase inhibitors. For Philadelphia chromosome-positive, T315I-negative ALL (monotherapy requests only), accelerated phase CML, or blast phase CML, attestation no other kinase inhibitors are indicated. |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to hematology and oncology   |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                |   |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# IDHIFA (enasidenib)

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## Products Affected

- IDHIFA

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of IDH2 mutation, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to hematology and oncology  |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |



# IMBRUVICA (ibrutinib)

## Products Affected

- IMBRUVICA ORAL CAPSULE
- IMBRUVICA ORAL SUSPENSION
- IMBRUVICA ORAL TABLET 140 MG, 280 MG, 420 MG

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Severe hepatic impairment (Child-Pugh class C), coadministration with strong CYP3A inducers  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of liver function testing or Child-Pugh score, pregnancy status for female patients of childbearing potential. For chronic graft-versus-host disease, documentation of treatment failure with any other systemic immunosuppressive agent. |
| <b>Age Restrictions</b>              |  |
| <b>Prescriber Restrictions</b>       | Restricted to hematology, oncology, and transplant specialty   |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                |  |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |

# IMKELDI (imatinib)

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## Products Affected

- IMKELDI

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, submission of clinical rationale or documentation detailing why the patient cannot use imatinib oral tablets. |
| Age Restrictions              |   |
| Prescriber Restrictions       | Restricted to allergy, dermatology, hematology, and oncology  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# IMMUNE GLOBULIN

## Products Affected

- GAMMAGARD
- GAMMAGARD S/D LESS IGA
- OCTAGAM INTRAVENOUS SOLUTION 1 GM/20ML, 10 GM/100ML, 10 GM/200ML, 2 GM/20ML, 2.5 GM/50ML, 20 GM/200ML, 5 GM/100ML, 5 GM/50ML
- PRIVIGEN

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | IgA-deficient patients with antibodies against IgA and a history of hypersensitivity.   |
| <b>Required Medical Information</b>  | Diagnosis of covered use. For ITP, submission of platelet count. For CLL, documentation of IgG level less than 600 mg/dL and recent history of serious bacterial infection requiring either oral or IV antibiotic therapy. For CIDP, unequivocal diagnosis and documentation patient is refractory, intolerant, or has a contraindication to systemic corticosteroids at therapeutic doses over at least 3 months. For passive immunization against varicella, confirmation that the patient is immunosuppressed and cannot receive varicella-zoster immune globulin. |
| <b>Age Restrictions</b>              |   |
| <b>Prescriber Restrictions</b>       |   |
| <b>Coverage Duration</b>             | For acute conditions/new starts, 3 months. For renewal of chronic conditions, 1 year.   |
| <b>Other Criteria</b>                | For each reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required. For IV formulations, covered as a Part B benefit if administered in the home for the treatment of primary immune deficiency. For any other combination of treatment site and indication, additional information may need to be submitted to determine if the immune globulin will be covered as a Part B or Part D benefit.   |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# INLYTA (axitinib)

## Products Affected

- INLYTA

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Uncontrolled hypertension, evidence of untreated brain metastasis, recent active gastrointestinal bleeding, coadministration with strong CYP3A4/5 inducers   |
| Required Medical Information  | Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential, attestation patient does not have uncontrolled hypertension and that axitinib will be used with either avelumab or pembrolizumab or, if being used as a single agent, documentation of at least one previous systemic therapy that was tried and failed. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |

# INQOVI (decitabine/cedazuridine)

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## Products Affected

- INQOVI

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to hematology and oncology   |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# INREBIC (fedratinib)

## Products Affected

- INREBIC

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Severe hepatic impairment, thiamine deficiency, coadministration with moderate or strong CYP3A4 inducers   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of thiamine level (see Other Criteria) and baseline platelet count, submission of current or previous therapies used to treat the condition (see Other Criteria).   |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to hematology and oncology  |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance/contraindication to ruxolitinib. If baseline thiamine level is low, coverage will be delayed until thiamine is repleted. |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |

# INVEGA INJECTABLE (paliperidone injectable suspension)

## Products Affected

- INVEGA HAFYERA
- INVEGA TRINZA INTRAMUSCULAR SUSPENSION  
 PREFILLED SYRINGE 273 MG/0.88ML, 410  
 MG/1.32ML, 546 MG/1.75ML, 819 MG/2.63ML

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Dementia-related psychosis  |
| <b>Required Medical Information</b>  | Diagnosis of covered use. For the 3-month injection, documentation of at least 4 months' treatment with 1-month paliperidone palmitate extended-release injectable suspension. For the 6-month injection, documentation of at least 4 months' treatment with 1-month paliperidone palmitate extended-release injectable suspension or at least one 3-month injection of 3-month paliperidone palmitate extended-release injectable suspension.                                      |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       |   |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                | A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# ITOVEBI (inavolisib)

## Products Affected

- ITOVEBI ORAL TABLET 3 MG, 9 MG

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, submission of genetic tumor testing confirming primary tumor type is HR-positive, HER2-negative, and PIK3CA-mutated, submission of current or previous therapies used to treat the condition (see Other Criteria), attestation that patient has locally advanced or metastatic disease, has not experienced disease progression on or following other PI3K inhibitors, and will be taking inavolisib concurrently with fulvestrant and palbociclib, submission of pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to oncology  |
| Coverage Duration             | 1 year  |
| Other Criteria                | For initial authorization, the patient must have tried and failed to have an adequate response to endocrine therapy (e.g., tamoxifen or an aromatase inhibitor) and must not have received prior chemotherapy for metastatic breast cancer. In addition, documentation of clinical rationale why abemaciclib, palbociclib, or ribociclib combined with endocrine therapy is not suitable for the patient must be submitted.   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | Yes   |



# IWILFIN (eflornithine)

## Products Affected

- IWILFIN

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            |   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, documentation patient demonstrated at least a partial response to prior multiagent, multimodal therapy including an anti-GD2 immunotherapy, submission of pregnancy status for female patients of childbearing potential. |
| <b>Age Restrictions</b>              |   |
| <b>Prescriber Restrictions</b>       | Restricted to oncology  |
| <b>Coverage Duration</b>             | 2 years (see Other Criteria)  |
| <b>Other Criteria</b>                | Per the prescribing information, the maximum length of therapy with eflornithine is 2 years and reauthorizations for use longer than 2 years will not be approved.  |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# JAKAFI (ruxolitinib)

## Products Affected

- JAKAFI

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | For myelofibrosis, platelet count less than $50 \times 10^9/L$   |
| Required Medical Information  | Diagnosis of covered use. For myelofibrosis, submission of baseline platelet count. For polycythemia vera, documented intolerance or inadequate response to hydroxyurea. For acute graft-versus-host disease, documented inadequate response to systemic corticosteroids. For chronic graft-versus-host-disease, documented failure of at least one previous line of systemic therapy. |
| Age Restrictions              |  |
| Prescriber Restrictions       | Restricted to hematology, oncology, and transplant specialty   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |

# JAYPIRCA (pirtobrutinib)

## Products Affected

- JAYPIRCA

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            |  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of current or previous therapies used to treat the condition (see Other Criteria), pregnancy status for female patients of childbearing potential.  |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to hematology and oncology  |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For initial authorization for mantle cell lymphoma, the patient must have tried and failed to have an adequate response to two previous lines of therapy, including a Bruton's tyrosine kinase (BTK) inhibitor. For initial authorization for chronic lymphocytic leukemia or small lymphocytic lymphoma, the patient must have tried and failed to have an adequate response to two previous lines of therapy, including a BTK inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor. |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |

# JOENJA (leniolisib)

## Products Affected

- JOENJA

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Pregnancy, moderate or severe hepatic impairment (Child-Pugh class B or C)  |
| <b>Required Medical Information</b>  | Diagnosis of covered use including submission of test confirming presence of a pathogenic variant of either PIK3CD or PIK3R1, submission of liver function testing or Child-Pugh score, confirmation of negative pregnancy status for female patients of childbearing potential or attestation from physician patient is not pregnant and will be using a highly effective method of contraception, attestation patient is not currently using an immunosuppressive medication. |
| <b>Age Restrictions</b>              | 12 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to specialists in genetic diseases or inborn errors of metabolism  |
| <b>Coverage Duration</b>             | Initially 6 months, then 1 year   |
| <b>Other Criteria</b>                | For each reauthorization, submission of objective documentation of a clinical benefit (e.g., normalization of lymphocyte subsets, normalization of lymphadenopathy, reduction in spleen size, etc.) or maintenance of a benefit previously achieved is required.  |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |

# JUXTAPID (lomitapide)

## Products Affected

- JUXTAPID ORAL CAPSULE 10 MG, 20 MG, 30 MG, 5 MG

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Heterozygous familial hypercholesterolemia, pregnancy, moderate or severe hepatic impairment (Child-Pugh class B or C), active liver disease, coadministration with moderate or strong CYP3A4 inhibitors  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, including at least one of the following criteria: (1) documented functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality, or (2) skin fibroblast LDL receptor activity less than 20% of normal, or (3) untreated total cholesterol (TC) above 500 mg/dL and triglycerides less than 300 mg/dL with both parents having a documented untreated TC above 250 mg/dL, submission of baseline lab values including ALT, AST, alkaline phosphatase, total bilirubin, baseline LDL-C, TC, apoB, and non-HDL-C, pregnancy status for female patients of childbearing potential, submission of current or previous therapies used to treat the condition (see Other Criteria). |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to cardiology, lipidology, and endocrinology with experience in and a focus on lipid management  |
| <b>Coverage Duration</b>             | Initially 6 months, then 1 year   |
| <b>Other Criteria</b>                | For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance/contraindication to evolocumab. For the first reauthorization, submission of reduction in LDL level from baseline is required. For each annual reauthorization, documented maintenance or further improvement of this clinical benefit is required.   |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# KERENDIA (finerenone)

## Products Affected

- KERENDIA

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Adrenal insufficiency, estimated glomerular filtration rate (eGFR) less than 25 mL/min/1.73 m <sup>2</sup> , serum potassium above 5.0 mEq/L at initiation of therapy, severe hepatic impairment (Child-Pugh class C), coadministration with strong CYP3A4 inhibitors or moderate or strong CYP3A4 inducers |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of eGFR, baseline serum potassium level, and current or previous therapies used to treat the condition (see Other Criteria).   |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       |   |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                | For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance to Farxiga or Jardiance. For each annual reauthorization, documented maintenance or further improvement of a clinical benefit is required.  |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# KETOCONAZOLE ORAL

## Products Affected

- *ketoconazole oral*

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Acute or chronic liver disease, treatment of fungal meningitis or fungal infections of the skin or nails  |
| <b>Required Medical Information</b>  | Diagnosis of culture-proven systemic blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, or paracoccidioidomycosis, submission of baseline ALT, AST, total bilirubin, alkaline phosphatase, prothrombin time and INR, prescriber attestation that the potential benefits of therapy outweigh the risks. |
| <b>Age Restrictions</b>              |   |
| <b>Prescriber Restrictions</b>       |   |
| <b>Coverage Duration</b>             | 6 months  |
| <b>Other Criteria</b>                |   |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |

# KISQALI (ribociclib)

## Products Affected

- KISQALI (200 MG DOSE)
- KISQALI (400 MG DOSE)
- KISQALI (600 MG DOSE)

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Congenital long QT syndrome, QTcF interval greater than or equal to 450 msec at treatment initiation, uncorrected hypokalemia or hypomagnesemia, coadministration with strong CYP3A4 inducers or drugs that can prolong the QT interval   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of genetic tumor testing confirming the primary tumor type is HR-positive, HER2-negative, submission of QTcF interval, serum potassium and magnesium drawn within the previous 6 months, pregnancy status for female patients of childbearing potential, attestation that the treatment regimen will include concomitant use of an aromatase inhibitor or fulvestrant. |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to oncology  |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                |   |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |



# KOSELUGO (selumetinib)

## Products Affected

- KOSELUGO

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Coadministration with moderate or strong CYP3A4 inducers  |
| Required Medical Information  | Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential.   |
| Age Restrictions              | Initiation: 2-17 years of age. Continuation: 2 years of age or older.   |
| Prescriber Restrictions       | Restricted to oncology  |
| Coverage Duration             | 1 year  |
| Other Criteria                | Selumetinib is indicated in pediatric patients and will not be approved for adults unless the patient started on the medication prior to 18 years of age. |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# KRAZATI (adagrasib)

## Products Affected

- KRAZATI

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Congenital long QT syndrome, coadministration with strong CYP3A4 inducers or drugs that prolong the QT interval   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of test confirming presence of KRAS G12C mutation. For non-small cell lung cancer, documentation of at least one previous therapy that was tried and failed. For colorectal cancer, documentation of previous therapy with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy. |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to oncology  |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                |   |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# LAPATINIB

## Products Affected

- *lapatinib ditosylate*

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Uncorrected hypokalemia or hypomagnesemia   |
| Required Medical Information  | Diagnosis of covered use, submission of genetic tumor testing confirming the primary tumor type is HER2-positive, submission of baseline potassium and magnesium levels, pregnancy status for female patients of childbearing potential, and attestation that the treatment regimen will include concomitant use of either capecitabine or letrozole. For patients who will be using lapatinib with capecitabine, submission of current or previous therapies used to treat the condition (see Other Criteria). |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to oncology  |
| Coverage Duration             | 1 year  |
| Other Criteria                | For initial authorization for lapatinib in combination with capecitabine, the patient must have had prior therapy with at least an anthracycline, a taxane, and trastuzumab.  |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | Yes   |

# LAZCLUZE (lazertinib)

## Products Affected

- LAZCLUZE ORAL TABLET 240 MG, 80 MG

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Coadministration with moderate or strong CYP3A4 inducers   |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, attestation that the medication will be used in combination with amivantamab and will be given with anticoagulant prophylaxis for the first four months of therapy, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# LENALIDOMIDE

## Products Affected

- *lenalidomide*

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Pregnancy, chronic lymphocytic leukemia (outside of a controlled clinical trial)   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, pregnancy status for female patients of childbearing potential. For maintenance therapy in patients with multiple myeloma following autologous hematopoietic stem cell transplant (auto-HSCT), submission of absolute neutrophil count (with the requirement it is at least 1,000/mcL) and platelet count (with the requirement it is at least 75,000/mcL). For mantle cell lymphoma, documentation of at least two prior therapies tried, one of which included bortezomib (or a documented contraindication to bortezomib). For follicular lymphoma and marginal zone lymphoma, submission of prior treatments tried and attestation medication will be coadministered with a rituximab product. For transfusion-dependent anemia due to myelodysplastic syndromes, documentation of a 5q cytogenetic abnormality. |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to hematology and oncology  |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                |  |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |

# LENVIMA (lenvatinib)

## Products Affected

- LENVIMA (10 MG DAILY DOSE)
- LENVIMA (12 MG DAILY DOSE)
- LENVIMA (14 MG DAILY DOSE)
- LENVIMA (18 MG DAILY DOSE)
- LENVIMA (20 MG DAILY DOSE)
- LENVIMA (24 MG DAILY DOSE)
- LENVIMA (4 MG DAILY DOSE)
- LENVIMA (8 MG DAILY DOSE)

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Uncorrected electrolyte abnormalities, uncontrolled hypertension  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of baseline blood pressure, pregnancy status for female patients of childbearing potential. For thyroid cancer, attestation patient is radioactive iodine-refractory or ineligible. For renal cell carcinoma, attestation drug will be coadministered with pembrolizumab or everolimus. If being coadministered with everolimus, submission of anti-angiogenic therapy tried and failed. For endometrial carcinoma, submission of test confirming the tumor is mismatch repair proficient or not microsatellite instability-high, submission of other systemic therapies tried and failed, attestation the candidate is not a candidate for surgery or radiation and drug will be coadministered with pembrolizumab. |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to oncology  |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                |   |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# LEUKINE (sargramostim, GM-CSF)

## Products Affected

- LEUKINE INJECTION SOLUTION RECONSTITUTED

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use.   |
| Age Restrictions              |   |
| Prescriber Restrictions       |   |
| Coverage Duration             | 3 months  |
| Other Criteria                | A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# L-GLUTAMINE

## Products Affected

- *l-glutamine oral packet*

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of sickle cell disease, submission of current or previous therapies used to treat the condition (see Other Criteria).                                |
| Age Restrictions              |  |
| Prescriber Restrictions       | Restricted to hematology   |
| Coverage Duration             | 1 year   |
| Other Criteria                | For initial authorization, the patient must be using, tried and failed to have an adequate response to, or had an intolerance/contraindication to hydroxyurea. |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |



# LIDOCAINE TRANSDERMAL PATCHES

## Products Affected

- *lidocaine external patch 5 %*
- *lidocan*
- *tridacaine ii*

| PA Criteria                   | Criteria Details              |
|-------------------------------|-------------------------------|
| Exclusion Criteria            |                               |
| Required Medical Information  | Diagnosis of covered use.     |
| Age Restrictions              | 18 years of age or older      |
| Prescriber Restrictions       |                               |
| Coverage Duration             | 1 year                        |
| Other Criteria                |                               |
| Indications                   | All FDA-approved Indications. |
| Off Label Uses                |                               |
| Part B Prerequisite           | No                            |
| Prerequisite Therapy Required | No                            |

# LIVTENCITY (maribavir)

## Products Affected

- LIVTENCITY

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use including a documented history of hematopoietic stem cell or solid organ transplant, submission of current or previous therapies used to treat the condition (see Other Criteria). |
| Age Restrictions              | 12 years of age or older  |
| Prescriber Restrictions       | Restricted to hematology, infectious diseases, oncology, and transplant specialty   |
| Coverage Duration             | 8 weeks   |
| Other Criteria                | For authorization, the patient must have tried and failed to have an adequate response to at least one of cidofovir, foscarnet, ganciclovir, or valganciclovir.   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# LODOCO (colchicine)

## Products Affected

- LODOCO

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Requests for the treatment of gout, renal failure, severe hepatic impairment, pre-existing blood dyscrasias, coadministration with strong CYP3A4 or P-glycoprotein inhibitors   |
| <b>Required Medical Information</b>  | Diagnosis, documented by either (1) prior acute coronary syndrome, or (2) prior ischemic stroke, transient ischemic attack, or carotid artery stenosis greater than 50%, or (3) prior coronary revascularization, or (4) proven coronary artery disease on invasive coronary angiography or computer tomography angiography, or (5) coronary-artery calcium score greater than or equal to 300 Agatston units, or (6) aortic atherosclerotic disease, or (7) symptomatic peripheral vascular disease, submission of estimated glomerular filtration rate (eGFR) or creatinine clearance (or serum creatinine, actual body weight, and height to calculate estimated creatinine clearance) with a requirement the eGFR or creatinine clearance is greater than or equal to 15 mL/min, and attestations patient (1) does not have severe hepatic impairment, and (2) has had a recent complete blood count and does not have evidence of any cytopenia, and (3) does not have NYHA functional Class 3 or 4 heart failure. |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to cardiology  |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                | For each annual reauthorization, submission of updated eGFR or creatinine clearance and complete blood count since the previous authorization is required.  |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |

# LONSURF (trifluridine/tipiracil)

## Products Affected

- LONSURF

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Moderate or severe hepatic impairment  |
| Required Medical Information  | Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For colorectal cancer, documentation of KRAS status and attestation patient was previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and, depending on KRAS status, an anti-EGFR therapy. For gastric cancer, attestation patient was previously treated with at least two lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |

# LORBRENA (lorlatinib)

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## Products Affected

- LORBRENA ORAL TABLET 100 MG, 25 MG

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Coadministration with strong CYP3A inducers, uncontrolled hypertension   |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of ALK-positive tumor, baseline blood pressure, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# LUMAKRAS (sotorasib)

## Products Affected

- LUMAKRAS

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Coadministration with strong CYP3A inducers, coadministration with proton pump inhibitors or H2 receptor antagonists  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of test confirming presence of KRAS G12C mutation. For non-small cell lung cancer, attestation patient has received at least one prior systemic therapy. For colorectal cancer, attestation patient was treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy. |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to oncology  |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                |   |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# LYBALVI (olanzapine/samidorphan)

## Products Affected

- LYBALVI

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Dementia-related psychosis, coadministration with opioids, levodopa, dopamine agonists, or strong CYP3A inducers, acute opioid withdrawal, end-stage renal disease   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of current or previous therapies used to treat the condition (see Other Criteria).  |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to neurology and psychiatry   |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance to both (1) generic olanzapine, including documentation showing a positive therapeutic benefit but unacceptable weight gain as a result of the drug, and (2) one other generic second-generation antipsychotic with low incidence of metabolic side effects (e.g., aripiprazole, lurasidone, ziprasidone). |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |

# LYNPARZA (olaparib)

## Products Affected

- LYNPARZA ORAL TABLET

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Coadministration with moderate or strong CYP3A inducers  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of current or previous therapies used to treat the condition (see Other Criteria), pregnancy status for female patients of childbearing potential. For ovarian cancer with a homologous recombination deficiency-positive status, submission of test confirming presence of BRCA mutation and/or genomic instability. For non-BRCA-mutated metastatic castration-resistant prostate cancer, submission of test confirming presence of germline or somatic homologous recombination repair gene mutation. For all other indications, submission of test confirming presence of BRCA mutation.  |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to oncology and urology   |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For initial authorization for ovarian cancer, attestation patient is in complete or partial response to platinum-based chemotherapy. If the patient has a homologous recombination deficiency-positive status, attestation patient will be using olaparib in combination with bevacizumab. For initial authorization for breast cancer, attestation patient has been previously treated with chemotherapy. If the patient has hormone receptor-positive tumor, attestation patient has been or cannot be treated with endocrine therapy. For initial authorization for pancreatic cancer, attestation patient has not progressed after at least 16 weeks of platinum-based chemotherapy. For initial authorization for castration-resistant prostate cancer, attestation patient has progressed after using abiraterone or enzalutamide or will be using olaparib in combination with abiraterone with a corticosteroid. |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |



# LYTGOBI (futibatinib)

## Products Affected

- LYTGOBI (12 MG DAILY DOSE)
- LYTGOBI (16 MG DAILY DOSE)
- LYTGOBI (20 MG DAILY DOSE)

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Coadministration with dual strong CYP3A4/P-glycoprotein inhibitors or inducers   |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of FGFR2 fusion or rearrangement, attestation previous systemic treatment has been tried, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |

# MAVYRET (glecaprevir/pibrentasvir)

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## Products Affected

- MAVYRET

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Moderate or severe hepatic impairment (Child-Pugh class B or C), coadministration with rifampin or atazanavir |
| Required Medical Information  | Diagnosis of covered use, laboratory confirmation of hepatitis C virus (HCV) infection and HCV genotype.      |
| Age Restrictions              |   |
| Prescriber Restrictions       |   |
| Coverage Duration             | Criteria for coverage duration will be applied consistent with current AASLD-IDSA guidance.                   |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# MECASERMIN

## Products Affected

- INCRELEX

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Patients with closed epiphyses, as a substitute for growth hormone (GH) for approved GH indications  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, documentation of primary insulin-like growth factor (IGF-1) deficiency or GH gene deletion in patients who have developed neutralizing antibodies to GH, submission of IGF-1 level and GH level. |
| <b>Age Restrictions</b>              |  |
| <b>Prescriber Restrictions</b>       | Restricted to endocrinology and nephrology   |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For each reauthorization, updated IGF-1 and GH levels since the previous authorization is required.  |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | No   |

# MEGESTROL IN OLDER PATIENTS

## Products Affected

- *megestrol acetate oral suspension 40 mg/ml, 625 mg/5ml*

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Pregnancy  |
| Required Medical Information  | Diagnosis of covered use.  |
| Age Restrictions              | PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger. |
| Prescriber Restrictions       | PA not required for hematology or oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# MEKINIST/TAFINLAR (trametinib/dabrafenib)

## Products Affected

- MEKINIST
- TAFINLAR

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of BRAF V600E or V600K mutation, pregnancy status for female patients of childbearing potential. For anaplastic thyroid cancer, BRAF V600E-mutated solid tumors, low-grade glioma, and adjuvant BRAF V600E- and/or V600K-mutated melanoma indications, confirmation that trametinib and dabrafenib will be co-administered. |
| Age Restrictions              |  |
| Prescriber Restrictions       | Restricted to oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# MEMANTINE/DONEPEZIL

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## Products Affected

- *memantine hcl-donepezil hcl*
- NAMZARIC ORAL CAPSULE EXTENDED RELEASE 24 HOUR 7-10 MG

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use, submission of documentation that the patient has tolerated donepezil 10 mg daily for a minimum of 1 month. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       |  |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |

# MIFEPRISTONE (CUSHING'S SYNDROME)

## Products Affected

- *mifepristone oral tablet 300 mg*

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Pregnancy, severe hepatic impairment, uncorrected hypokalemia, female patients with a history of unexplained vaginal bleeding or endometrial hyperplasia with atypia or endometrial carcinoma, patients using systemic corticosteroids for life-saving purposes, coadministration with strong CYP3A4 inducers, simvastatin, lovastatin, or CYP3A substrates with narrow therapeutic ranges |
| <b>Required Medical Information</b>  | Diagnosis of covered use, attestation surgery is not an option for the patient or has not been curative, documentation patient has type 2 diabetes mellitus or glucose intolerance, submission of Child-Pugh score, pregnancy status for female patients of childbearing potential.  |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to endocrinology  |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.   |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | No   |

# MIGLUSTAT

## Products Affected

- *miglustat*
- *yargesa*

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Severe renal impairment (CrCl less than 30 mL/min)   |
| Required Medical Information  | Diagnosis of covered use, documentation that enzyme replacement is not a therapeutic option (e.g., allergy, poor central venous access, hypersensitivity), submission of creatinine clearance (or serum creatinine, actual body weight, and height to calculate estimated creatinine clearance). |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       |  |
| Coverage Duration             | 1 year   |
| Other Criteria                | For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.   |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |



# MODEYSO (dordaviprone)

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## Products Affected

- MODEYSO

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Coadministration with moderate or strong CYP3A4 inducers  |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming an H3K27M mutation, pregnancy status for female patients of childbearing potential, documentation of at least one previous therapy. |
| Age Restrictions              |   |
| Prescriber Restrictions       | Restricted to oncology  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | Yes   |

# MYTESI (crofelemer)

## Products Affected

- MYTESI

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use, attestation infectious causes of diarrhea have been ruled out.   |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       |  |
| Coverage Duration             | 1 year   |
| Other Criteria                | For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required. |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# NERLYNX (neratinib)

## Products Affected

- NERLYNX

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Coadministration with proton pump inhibitors, strong CYP3A4 inhibitors, moderate CYP3A4 and P-glycoprotein dual inhibitors, or moderate or strong CYP3A4 inducers   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of genetic tumor testing confirming the primary tumor type is HER2-positive, confirmation member has completed adjuvant trastuzumab-based therapy or will be using in combination with capecitabine, pregnancy status for female patients of childbearing potential. For advanced or metastatic breast cancer, submission of previous anti-HER2 regimens used. |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to oncology  |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                |   |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# NILOTINIB

## Products Affected

- DANZITEN
- *nilotinib hcl*

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Uncorrected hypokalemia or hypomagnesemia, long QT syndrome, coadministration with drugs that prolong the QT interval, proton pump inhibitors, or strong CYP3A4 inducers |
| <b>Required Medical Information</b>  | Diagnosis of covered use, confirmation of positive Philadelphia chromosome (Ph) status, baseline serum potassium and magnesium levels.                                   |
| <b>Age Restrictions</b>              |  |
| <b>Prescriber Restrictions</b>       | Restricted to hematology and oncology  |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                |  |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | No   |

# NINLARO (ixazomib)

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## Products Affected

- NINLARO

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Coadministration with strong CYP3A4 inducers   |
| Required Medical Information  | Diagnosis of covered use, documentation that medication will be administered concomitantly with lenalidomide and dexamethasone, documentation of prior therapy regimen for multiple myeloma, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to hematology and oncology  |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# NITISINONE

## Products Affected

- *nitisinone*

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of succinylacetone in urine or plasma.   |
| Age Restrictions              |   |
| Prescriber Restrictions       |   |
| Coverage Duration             | Initially 6 months, then 1 year   |
| Other Criteria                | For each reauthorization, submission of objective documentation of a clinical benefit, such as reductions in urine succinylacetone level, alpha-fetoprotein level, serum tyrosine level, or serum phenylalanine level, or maintenance of a benefit previously achieved is required. |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# NUCALA (mepolizumab)

## Products Affected

- NUCALA SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- NUCALA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/ML
- NUCALA SUBCUTANEOUS SOLUTION RECONSTITUTED

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Regular (non-eosinophilic) granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA)  |
| <b>Required Medical Information</b> | Diagnosis of covered use. For asthma, chronic rhinosinusitis with nasal polyps (CRSwNP), and hypereosinophilic syndrome (HES), submission of current and previous therapies used to treat the condition (see Other Criteria). For asthma, (1) documentation of a pre-bronchodilator FEV1 less than 80% predicted in adults, or less than 90% in children, and (2) submission of blood eosinophil (eos) count of at least 150 cells/mcL obtained within 6 weeks of therapy initiation or at least 300 cells/mcL within 12 months of therapy initiation. For CRSwNP, (1) documentation of evidence of nasal polyps, and (2) attestation that patient has symptomatic nasal congestion. For eosinophilic granulomatosis with polyangiitis, documentation of (1) an eos percentage greater than or equal to 10% or an absolute eos count greater than 1000 cells/cubic millimeter from the previous 6 weeks, and (2) disease lasting at least 6 months that is relapsed or refractory to oral corticosteroids and/or immunosuppressive therapies. For HES, documentation of (1) uncontrolled disease defined as a history of at least 2 flares requiring systemic therapy within the past 12 months and a blood eos count of at least 1000 cells/mcL from the previous 6 weeks, and (2) attestation disease does not have an identifiable non-hematologic secondary cause. |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | Restricted to allergy, hematology, immunology, otorhinolaryngology, pulmonology, and rheumatology  |
| <b>Coverage Duration</b>            | 1 year   |

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Other Criteria                | <p>For initial authorization for asthma, patient must be on a drug regimen as recommended by GINA guidelines prior to the use of biologic medications, consisting of, at a minimum, a maximally-tolerated dose of inhaled corticosteroid (ICS), a long-acting beta-agonist (LABA), and a long-acting antimuscarinic antagonist (LAMA), and the provider must attest this therapy will be continued after starting mepolizumab. For initial authorization for CRSwNP, patient must have tried an intranasal corticosteroid for at least two months (and provider must attest this will be continued after starting mepolizumab), have a contraindication to intranasal corticosteroids, or documentation must be submitted as to why this therapy is not otherwise advisable. For initial authorization for HES, patient must have been using a course of oral corticosteroids, cytotoxic therapy, or immunosuppressive therapy for at least the previous 4 weeks. For each reauthorization for asthma, confirmation patient is still using triple ICS-LABA-LAMA inhaler therapy is required. For each reauthorization for asthma, EGPA, or HES, documentation of a clinical benefit (e.g., reduction from baseline in rate of annual exacerbations or severe exacerbations, systemic corticosteroid dose, or disease symptom score, improvement in FEV1) or maintenance of a benefit previously achieved, is required. For each reauthorization for CRSwNP, confirmation patient is still using an intranasal corticosteroid, unless contraindicated, and documentation of a clinical benefit (e.g., reduction from baseline in nasal congestion, nasal polyp score or systemic corticosteroid dose) or maintenance of a benefit previously achieved is required. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.</p> |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | Yes   |



# NUEDEXTA (dextromethorphan/quinidine)

## Products Affected

- NUEDEXTA

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Agitation or Alzheimer's disease without pseudobulbar affect, prolonged QT interval, congenital long QT syndrome, heart failure, history suggestive of torsades de pointes, AV block without implanted pacemaker, uncorrected hypokalemia or hypomagnesemia, administration of non-selective monoamine oxidase inhibitors within 14 days of initiation   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of baseline serum potassium and magnesium levels. In patients with an increased risk of QT prolongation, including patients taking drugs that prolong the QT interval, taking moderate or strong CYP3A4 inhibitors, with left ventricular hypertrophy, or with left ventricular dysfunction, submission of electrocardiographic (ECG) evaluation of baseline QT interval. |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to neurology and psychiatry   |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For each annual reauthorization, submission of updated potassium and magnesium levels and confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.  |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | No   |

# NUPLAZID (pimavanserin)

## Products Affected

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Psychosis unrelated to Parkinson's disease psychosis, cardiac arrhythmias, symptomatic bradycardia, congenital QT prolongation, coadministration with moderate or strong CYP3A4 inducers or drugs that prolong the QT interval, uncorrected hypokalemia or hypomagnesemia |
| Required Medical Information  | Diagnosis of covered use, submission of baseline serum potassium and magnesium levels.  |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       |   |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# ODOMZO (sonidegib)

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## Products Affected

- ODOMZO

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Pregnancy, coadministration with strong CYP3A4 inhibitors or moderate or strong CYP3A4 inducers   |
| Required Medical Information  | Diagnosis of covered use, attestation patient is not a candidate for surgery or radiation therapy or carcinoma has recurred following surgery or radiation therapy, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to oncology  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# OFEV (nintedanib)

## Products Affected

- OFEV

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Moderate or severe hepatic impairment (Child-Pugh class B or C), coadministration of a dual P-glycoprotein/CYP3A4 inducer   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of liver function tests or Child-Pugh score, pregnancy status for female patients of childbearing potential. For chronic fibrosing interstitial lung diseases with a progressive phenotype and systemic sclerosis-associated interstitial lung disease, submission of HRCT scan showing fibrosis of the lungs within the previous 12 months. |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to pulmonology and rheumatology  |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                | For each annual reauthorization, submission of updated liver function testing or Child-Pugh score since the previous authorization and confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.  |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |

## OGSIVEO (nirogacestat)

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### Products Affected

- OGSIVEO ORAL TABLET 100 MG, 150 MG, 50 MG

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Coadministration with moderate or strong CYP3A inhibitors or inducers, proton pump inhibitors, or H2 receptor antagonists                       |
| Required Medical Information  | Diagnosis of covered use with documentation of tumor progression, submission of pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to oncology and sarcoma specialty  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# OJEMDA (tovorafenib)

## Products Affected

- OJEMDA

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Coadministration with moderate or strong CYP2C8 inhibitors or inducers   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of test confirming presence of BRAF V600 mutation or BRAF gene fusion or rearrangement, documentation of previous systemic therapy/therapies for pediatric low-grade glioma tried and failed with a minimum of one previous therapy necessary for approval, pregnancy status for female patients of childbearing potential. If genetic testing does not reveal a BRAF gene fusion or rearrangement, documentation of previous intolerance to, contraindication to, or other reason why the patient cannot use the combination of trametinib and dabrafenib. |
| <b>Age Restrictions</b>              | Initiation: 21 years of age or younger (see Other Criteria)  |
| <b>Prescriber Restrictions</b>       | Restricted to oncology   |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | Tovorafenib is indicated as therapy in children and young adults and will not be approved for adults unless the patient started on the medication prior to 22 years of age.  |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |

## OJJAARA (mometotinib)

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### Products Affected

- OJJAARA ORAL TABLET 100 MG, 150 MG, 200 MG

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Active infection, uncontrolled acute or chronic liver disease |
| Required Medical Information  | Diagnosis of covered use.                                     |
| Age Restrictions              | 18 years of age or older                                      |
| Prescriber Restrictions       | Restricted to hematology and oncology                         |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.                                 |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# ONUREG (azacitidine)

## Products Affected

- ONUREG

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Diagnosis of myelodysplastic syndrome  |
| Required Medical Information  | Diagnosis of covered use, documentation patient achieved first complete remission or complete remission with incomplete blood count recovery following intensive induction chemotherapy and attestation patient cannot complete intensive curative therapy, submission of absolute neutrophil count (with the requirement it is at least 500/mcL), submission of pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to hematology and oncology  |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |



## ORIAHNN (elagolix/estradiol/norethindrone)

### Products Affected

- ORIAHNN

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Pregnancy, known liver impairment or disease, known osteoporosis, undiagnosed abnormal uterine bleeding, women who are at increased risk of, have a history of, or currently have thrombotic or thromboembolic disorders (including women over 35 years of age who smoke and women with uncontrolled hypertension), current/history of breast cancer or other hormone-sensitive cancer |
| <b>Required Medical Information</b>  | Diagnosis of covered use, attestation patient is premenopausal, submission of baseline blood pressure, pregnancy status for female patients of childbearing potential.   |
| <b>Age Restrictions</b>              |  |
| <b>Prescriber Restrictions</b>       | Restricted to endocrinology and gynecology   |
| <b>Coverage Duration</b>             | 2 years (see Other Criteria)   |
| <b>Other Criteria</b>                | Use of this drug for more than 2 years increases risk of bone loss and requests for therapy for more than 2 years will not be approved.  |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | No   |

# ORILISSA (elagolix)

## Products Affected

- ORILISSA ORAL TABLET 150 MG, 200 MG

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Pregnancy, severe hepatic impairment (Child-Pugh class C), known osteoporosis, coadministration with OATP1B1 inhibitors   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, attestation patient is premenopausal and will be using non-hormonal contraception during therapy, submission of liver function testing or Child-Pugh score, pregnancy status for female patients of childbearing potential. If the patient has previously used elagolix, submission of dose used and number of total months of prior use.   |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to endocrinology and gynecology  |
| <b>Coverage Duration</b>             | Up to 24 months based on dose and coexisting conditions (see Other Criteria)  |
| <b>Other Criteria</b>                | Due to increased risk of bone loss, maximum duration of use is limited based on dose and coexisting conditions. For (1) endometriosis with dyspareunia where dose will be 200 mg twice daily, or (2) women with moderate hepatic impairment, the maximum duration of use is 6 months. Requests for use greater than 6 months will not be approved in these situations. For (3) endometriosis without dyspareunia, 150 mg daily for 24 months. Requests for use greater than 24 months will not be approved in this situation. |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |

## ORSERDU (elacestrant)

### Products Affected

- ORSERDU

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Severe hepatic impairment (Child-Pugh class C), coadministration with moderate or strong CYP3A inhibitors or inducers   |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming the primary tumor type is ER-positive, HER2-negative, and ESR1-mutated, submission of liver function testing or Child-Pugh score, attestation patient had disease progression after at least one prior endocrine therapy. For female patients, attestation patient is postmenopausal. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to oncology  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | Yes   |

# OXYBATE SALT MEDICATIONS

## Products Affected

- *sodium oxybate*

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Coadministration with sedative hypnotics, diagnosis of insomnia   |
| <b>Required Medical Information</b>  | Diagnosis of covered use confirmed with documentation from a sleep study. For adults with excessive daytime sleepiness associated with narcolepsy, submission of current or previous therapies used to treat the condition (see Other Criteria).  |
| <b>Age Restrictions</b>              | 7 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to neurology, psychiatry, and sleep medicine   |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                | For initial authorization for adults with excessive daytime sleepiness associated with narcolepsy, the patient must have tried and failed to have an adequate response to or had an intolerance/contraindication to both (1) armodafinil or modafinil, and (2) solriamfetol. For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required. |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# PANRETIN (alitretinoin)

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## Products Affected

- PANRETIN

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Pregnancy, instances where systemic Kaposi sarcoma therapy is required (more than 10 new Kaposi's sarcoma lesions in the prior month, symptomatic lymphedema, symptomatic pulmonary Kaposi sarcoma, or symptomatic visceral involvement) |
| Required Medical Information  | Diagnosis of covered use.  |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to dermatology and oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# PARKINSON'S DISEASE "OFF" EPISODE (AS NEEDED) THERAPIES

## Products Affected

- *apomorphine hcl subcutaneous*
- INBRIJA

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | For Inbrija, administration of non-selective monoamine oxidase inhibitors within 14 days of initiation, asthma, COPD, or other chronic underlying lung disease.  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, attestation patient is experiencing "off" episodes despite carbidopa/levodopa therapy, submission of current or previous therapies used to treat the condition (see Other Criteria).   |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to neurology  |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance to medications from at least two different classes that can help to reduce off episodes (COMT inhibitors, dopamine agonists, monoamine oxidase B inhibitors), unless contraindicated. For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required. |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |

# PAZOPANIB

## Products Affected

- *pazopanib hcl*

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Severe hepatic impairment, uncontrolled hypertension, uncorrected hypokalemia, hypocalcemia, or hypomagnesemia, coadministration with strong CYP3A4 inducers, proton pump inhibitors, H2-receptor antagonists, or drugs that can prolong the QT interval  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of baseline blood pressure, serum potassium, calcium, and magnesium levels, pregnancy status for female patients of childbearing potential. For soft tissue sarcoma, submission of previous chemotherapy regimen(s). |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to oncology  |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                |   |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |

# PEGFILGRASTIM

## Products Affected

- UDENYCA
- UDENYCA ONBODY

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of FDA-approved indication.   |
| Age Restrictions              |   |
| Prescriber Restrictions       |   |
| Coverage Duration             | 6 months  |
| Other Criteria                | A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |



# PEMAZYRE (pemigatinib)

## Products Affected

- PEMAZYRE ORAL TABLET 13.5 MG, 4.5 MG, 9 MG

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Coadministration with moderate or strong CYP3A4 inducers  |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of either FGFR1 rearrangement or FGFR2 fusion or rearrangement depending on the indication, attestation patient has used previous systemic treatment for the indication, submission of pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to hematology and oncology   |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# PHEBURANE (sodium phenylbutyrate)

## Products Affected

- PHEBURANE

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use, submission of baseline fasting plasma ammonia level, submission of current or previous therapies used to treat the condition (see Other Criteria).   |
| Age Restrictions              |  |
| Prescriber Restrictions       | Restricted to providers experienced in the treatment of urea cycle disorders   |
| Coverage Duration             | 1 year   |
| Other Criteria                | For initial authorization, the patient must have had a documented trial of or had an intolerance/contraindication to generic sodium phenylbutyrate. For each annual reauthorization, submission of objective documentation of a symptomatic or clinical benefit or maintenance of a benefit previously achieved is required. |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |

# PIQRAY (alpelisib)

## Products Affected

- PIQRAY (200 MG DAILY DOSE)
- PIQRAY (250 MG DAILY DOSE)
- PIQRAY (300 MG DAILY DOSE)

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Coadministration with strong CYP3A4 inducers  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of genetic tumor testing confirming the primary tumor type is HR-positive, HER2-negative, and PIK3CA-mutated, attestation that patient has advanced or metastatic disease and will be taking concurrently with fulvestrant, submission of at least one endocrine-based (e.g., anastrozole, exemestane, letrozole, tamoxifen, etc.) regimen tried and failed, pregnancy status for female patients of childbearing potential. |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to oncology  |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                |   |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# PIRFENIDONE

## Products Affected

- *pirfenidone oral tablet 267 mg, 801 mg*

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | End-stage renal disease on dialysis, severe hepatic impairment (Child-Pugh class C)  |
| Required Medical Information  | Diagnosis of covered use, submission of liver function tests or Child-Pugh score.  |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to pulmonology  |
| Coverage Duration             | 1 year   |
| Other Criteria                | For each annual reauthorization, submission of updated liver function testing or Child-Pugh score since the previous authorization and confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required. |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# POMALYST (pomalidomide)

## Products Affected

- POMALYST

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Pregnancy  |
| Required Medical Information  | Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For multiple myeloma, documentation patient has previously used lenalidomide and a proteasome inhibitor and patient has demonstrated disease progression on or within 60 days of the completion of the previous therapy. For Kaposi sarcoma, attestation patient is HIV-negative or patient has failed highly-active antiretroviral therapy. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to hematology and oncology  |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |

# PRETOMANID

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## Products Affected

- PRETOMANID

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Inability to use bedaquiline or linezolid, drug-sensitive tuberculosis, coadministration with moderate or strong CYP3A4 inducers |
| Required Medical Information  | Diagnosis of covered use, attestation pretomanid will be used in combination with bedaquiline and linezolid.                     |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to infectious diseases and pulmonology  |
| Coverage Duration             | 26 weeks   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# PREVYMIS (letermovir)

## Products Affected

- PREVYMIS ORAL TABLET

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Severe hepatic impairment (Child-Pugh class C), coadministration with ergot alkaloids, pimozide, or pitavastatin or simvastatin when coadministered with cyclosporine   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of day number post-transplant. For use after kidney transplant, documentation patient is high risk, defined as donor CMV seropositive/recipient CMV seronegative (D+/R-), submission of explanation why valganciclovir is contraindicated or cannot be used for prophylaxis. |
| <b>Age Restrictions</b>              |   |
| <b>Prescriber Restrictions</b>       | Restricted to hematology, infectious diseases, oncology, and transplant speciality  |
| <b>Coverage Duration</b>             | 100 days post-HSCT or 200 days post-kidney transplant or post-HSCT at risk for late CMV infection   |
| <b>Other Criteria</b>                |   |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |

# PRIOR AUTHORIZATION TO OVERRIDE SPECIALTY RESTRICTIONS

## Products Affected

- CORLANOR ORAL SOLUTION
- *diclofenac sodium external gel 3 %*
- *ivabradine hcl oral tablet 5 mg, 7.5 mg*
- NAYZILAM
- PEGASYS SUBCUTANEOUS SOLUTION 180 MCG/ML
- PEGASYS SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- VALTOCO 10 MG DOSE
- VALTOCO 15 MG DOSE NASAL LIQUID THERAPY PACK 2 X 7.5 MG/0.1ML
- VALTOCO 20 MG DOSE NASAL LIQUID THERAPY PACK 2 X 10 MG/0.1ML
- VALTOCO 5 MG DOSE

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use. Drugs in this policy require prior authorization but are exempted from this requirement if prescribed by certain specialists (see Prescriber Restriction).   |
| Age Restrictions              |  |
| Prescriber Restrictions       | (1) for ivabradine: cardiology exempt, (2) for diclofenac 3% gel: dermatology and oncology exempt, (3) for Nayzilam and Valtoco: neurology exempt, (4) for Pegasys: gastroenterology, hepatology, and infectious diseases exempt |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |



# PROLASTIN-C (alpha-1-proteinase inhibitor)

## Products Affected

- PROLASTIN-C INTRAVENOUS SOLUTION

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Individuals with immunoglobulin A (IgA) deficiency who have known antibodies against IgA  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of pre-treatment alpha-1-antitrypsin (AAT) showing levels below 11 mmol/L (80 mg/dL), confirmation that patient has clinically evident emphysema secondary to congenital alpha-1-PI deficiency by submission of pulmonary function testing (e.g., spirometry or body plethysmography), X-ray radiography, or diffusing capacity of the lung for carbon monoxide (DLCO).  |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to pulmonology   |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                | For each reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |

# PROMETHAZINE IN OLDER PATIENTS

## Products Affected

- *promethazine hcl oral solution 6.25 mg/5ml*
- *promethazine hcl oral tablet*
- *promethazine hcl rectal suppository 12.5 mg, 25 mg*
- PROMETHEGAN RECTAL SUPPOSITORY 25 MG, 50 MG

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use. For allergic conditions, documentation must be submitted showing patient has tried and failed or had an inadequate response to a second-generation antihistamine. |
| Age Restrictions              | PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger.  |
| Prescriber Restrictions       |   |
| Coverage Duration             | 1 year  |
| Other Criteria                | Promethazine is a potent anticholinergic considered high-risk in older patients due to risks of confusion, dry mouth, constipation, and decreased clearance with advanced age.              |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | Yes   |

# PROSTATE CANCER ORAL MEDICATIONS

## Products Affected

- AKEEGA
- ERLEADA
- NUBEQA
- XTANDI

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | For Akeega, severe hepatic impairment (Child-Pugh class C), uncontrolled hypertension, uncontrolled hypokalemia  |
| <b>Required Medical Information</b>  | Diagnosis of covered use. For Nubeqa, submission of current or previous therapies used to treat the condition (see Other Criteria). For Akeega, submission of test confirming presence of deleterious BRCA mutation, Child-Pugh score or liver function testing, baseline blood pressure reading, and serum potassium level. |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to oncology and urology   |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For initial authorization of Nubeqa, the patient must have tried and failed to have an adequate response or had an intolerance to both Erleada and Xtandi.   |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |

# PULMONARY HYPERTENSION MEDICATIONS

## Products Affected

- *alyq*
- *ambrisentan oral tablet 10 mg, 5 mg*
- *bosentan oral tablet 125 mg, 62.5 mg*
- OPSUMIT
- ORENITRAM
- ORENITRAM MONTH 1
- ORENITRAM MONTH 2
- ORENITRAM MONTH 3
- *sildenafil citrate oral suspension reconstituted*
- *sildenafil citrate oral tablet 20 mg*
- *tadalafil (pah)*

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | For ambrisentan, bosentan, or Opsumit, pregnancy. For ambrisentan or Orenitram, moderate or severe hepatic impairment. For tadalafil, severe hepatic impairment or creatinine clearance below 30 mL/min or on hemodialysis. For ambrisentan, idiopathic pulmonary fibrosis.   |
| <b>Required Medical Information</b>  | Diagnosis of covered use confirmed by right heart catheterization, submission of mean pulmonary arterial pressure greater than 20 mm Hg at rest, pulmonary arterial wedge pressure less than or equal to 15 mm Hg, pulmonary vascular resistance greater than 2 Woods units, and attestation patient is WHO Group 1. For ambrisentan, bosentan, or Opsumit, submission of pregnancy status for female patients of childbearing potential. For Opsumit only, submission of current or previous therapies used to treat the condition (see Other Criteria). |
| <b>Age Restrictions</b>              | For all drugs in this policy except bosentan, 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to cardiology and pulmonology  |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                | For initial authorization of Opsumit, the patient must have tried and failed to have an adequate response to or had an intolerance to ambrisentan or bosentan.  |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

## QINLOCK (ripretinib)

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### Products Affected

- QINLOCK

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Uncontrolled hypertension, coadministration with strong CYP3A inducers   |
| Required Medical Information  | Diagnosis of covered use, submission of previous kinase inhibitor therapies, baseline blood pressure reading, baseline left ventricular ejection fraction with a requirement it is greater than or equal to 50%, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |

# RADICAVA ORS (edaravone)

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## Products Affected

- RADICAVA ORS
- RADICAVA ORS STARTER KIT

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, submission of ALS Functional Rating Scale - Revised (ALSFRS-R) scoring with the requirement the patient has scores of 2 points or better on each of the 12 individual ALSFRS-R items. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to neurology   |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# RECORLEV (levoketoconazole)

## Products Affected

- RECORLEV

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Treatment of fungal infection, cirrhosis, acute, poorly-controlled chronic, or extensive metastatic liver disease, baseline AST or ALT greater than 3 times the upper limit of normal, recurrent symptomatic cholelithiasis, a prior history of drug-induced liver injury due to ketoconazole or any azole antifungal therapy that required discontinuation of treatment, prolonged QTcF interval greater than 470 msec at baseline, history of torsades de pointes, ventricular tachycardia, ventricular fibrillation, prolonged QT syndrome, coadministration with drugs that cause QT prolongation associated with ventricular arrhythmias |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of 24-hour urine free cortisol (UFC) level demonstrating a baseline value more than 1.5 times the upper limit of normal (50 micrograms or 145 nmol), attestation pituitary gland surgery is not an option for the patient or has not been curative, electrocardiogram (including QTcF), and liver function tests all performed within 3 months of prior authorization request, documentation patient tried and failed at least one other therapy for Cushing's syndrome (e.g., mifepristone, pasireotide).   |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to endocrinology   |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                | For each reauthorization, documentation of clinically relevant response to therapy, including but not limited to reduction of 24-hour UFC level, or maintenance of a benefit previously achieved, is required.  |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# REPATHA (evolocumab)

## Products Affected

- REPATHA
- REPATHA PUSHTRONEX SYSTEM
- REPATHA SURECLICK

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            |   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of current or previous therapies used to treat the condition (see Other Criteria).   |
| <b>Age Restrictions</b>              | 10 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to cardiology, endocrinology, or providers focusing in treatment of cardiovascular risk management or lipid disorders  |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                | For initial authorization for reducing major adverse cardiovascular events or heterozygous familial hypercholesterolemia, the patient must (1) have tried and failed to achieve an LDL below 70 mg/dL despite at least 8 weeks of high-intensity statin therapy, or (2) experienced rhabdomyolysis while using a statin, or (3) had a skeletal muscle intolerance to both atorvastatin and rosuvastatin that resolved upon discontinuation. For initial authorization for homozygous familial hypercholesterolemia, the patient must (1) have tried and failed to have an adequate response to achieve an LDL below goal despite at least 8 weeks of high-intensity statin therapy, or (2) experienced rhabdomyolysis while using a statin, or (3) had an skeletal muscle intolerance to both atorvastatin and rosuvastatin that resolved upon discontinuation, or (4) are statin-intolerant for reasons other than (2) or (3). |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |



# RETACRIT (epoetin alfa-epbx)

## Products Affected

- RETACRIT INJECTION SOLUTION 10000 UNIT/ML, 2000 UNIT/ML, 20000 UNIT/ML, 3000 UNIT/ML, 4000 UNIT/ML, 40000 UNIT/ML

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            |   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of hemoglobin level less than 10 g/dL (at initial submission for non-surgery indications only), attestation serum iron, total iron-binding capacity (TIBC), and transferrin saturation level have been assessed within 30 days of request date, documentation that the patient does not have uncontrolled hypertension.  |
| <b>Age Restrictions</b>              |   |
| <b>Prescriber Restrictions</b>       |   |
| <b>Coverage Duration</b>             | ESRD-related conditions or anemia due to zidovudine therapy: 1 year. All other indications: 90 days.  |
| <b>Other Criteria</b>                | A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |

# RETEVMO (selpercatinib)

## Products Affected

- RETEVMO ORAL TABLET 120 MG, 160 MG, 40 MG, 80 MG

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Uncontrolled hypertension, coadministration with moderate or strong CYP3A inducers   |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of RET gene fusion or mutation, baseline blood pressure reading, pregnancy status for female patients of childbearing potential. For RET fusion-positive thyroid cancer, attestation patient is radioactive iodine-refractory or ineligible. For solid tumors with a RET gene fusion, documentation of previous systemic therapy tried or reason why patient has no satisfactory alternative treatment options. |
| Age Restrictions              |  |
| Prescriber Restrictions       | Restricted to oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# REVCOVI (elapegademase-lvlr)

## Products Affected

- REVCOVI

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Severe thrombocytopenia  |
| Required Medical Information  | Diagnosis of covered use confirmed by either biochemical testing showing less than 1% of adenosine deaminase (ADA) catalytic activity in red blood cells or genetic testing showing biallelic ADA pathogenic variants, submission of baseline plasma ADA level (if genetic testing was submitted as confirmation of diagnosis) and platelet count. |
| Age Restrictions              |  |
| Prescriber Restrictions       | Restricted to hematology, immunology, and specialists in genetic diseases  |
| Coverage Duration             | 1 year   |
| Other Criteria                | For each annual reauthorization, submission of updated plasma ADA level demonstrating an improvement from baseline and platelet count is required.   |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# REVUFORJ (revumenib)

## Products Affected

- REVUFORJ ORAL TABLET 110 MG, 160 MG, 25 MG

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | QTcF interval greater than 450 msec at treatment initiation, white blood cell (WBC) count greater than $25 \times 10^9/L$ , uncorrected hypokalemia or hypomagnesemia, coadministration with moderate or strong CYP3A4 inducers  |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of a lysine methyltransferase 2A gene (KMT2A) translocation that is not a 11q23 partial tandem duplication, submission of baseline QTcF interval, serum potassium, serum magnesium, baseline WBC count, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              |  |
| Prescriber Restrictions       | Restricted to hematology and oncology  |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

## REZDIFFRA (resmetirom)

### Products Affected

- REZDIFFRA

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Decompensated cirrhosis, moderate or severe hepatic impairment  |
| Required Medical Information  | Diagnosis of covered use, confirmation patient has F2 or F3 fibrosis by either liver biopsy, magnetic resonance elastography, or vibration-controlled elastography, submission of liver function testing or Child-Pugh score.   |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to gastroenterology and hepatology   |
| Coverage Duration             | 1 year  |
| Other Criteria                | For the first reauthorization, documentation confirming resolution of metabolic dysfunction-associated steatohepatitis or improvement or stabilization of fibrosis stage from baseline, as assessed by biopsy or noninvasive testing, is required. For each annual reauthorization, documented maintenance of a clinical benefit is required. |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# REZLIDHIA (olutasidenib)

## Products Affected

- REZLIDHIA

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Coadministration with moderate or strong CYP3A inducers  |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of IDH1 mutation, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to hematology and oncology  |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# REZUROCK (belumosudil)

## Products Affected

- REZUROCK

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Moderate or severe hepatic impairment (Child-Pugh class B or C) without liver graft-versus-host disease   |
| Required Medical Information  | Diagnosis of covered use, submission of at least 2 previous therapies tried and failed for chronic graft-versus-host disease, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 12 years of age or older  |
| Prescriber Restrictions       | Restricted to hematology, oncology, and transplant specialty  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | Yes   |

# RIVFLOZA (nedosiran)

## Products Affected

- RIVFLOZA

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Estimated glomerular filtration rate (eGFR) less than 30 mL/min/1.73 m <sup>2</sup>   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, documentation of AGXT mutation confirmed by liver enzyme analysis or genetic testing, submission of 24-hour urinary oxalate (Uox) excretion with a requirement it is greater than or equal to 0.7 mmol (normalized to body surface area if patient is under 18 years of age) and eGFR, attestation patient has not received a prior kidney or liver transplant, attestation patient will not be using in combination with lumasiran (Oxlumo). |
| <b>Age Restrictions</b>              |   |
| <b>Prescriber Restrictions</b>       | Restricted to nephrology and urology  |
| <b>Coverage Duration</b>             | Initially 6 months, then 1 year   |
| <b>Other Criteria</b>                | For the first reauthorization, documentation of clinically relevant response to therapy as evidenced by reduced Uox or plasma oxalate levels is required. For each annual reauthorization, documented maintenance of a clinical benefit is required.  |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |



# ROMVIMZA (vimseltinib)

## Products Affected

- ROMVIMZA

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Active liver or biliary tract disease (including increased ALP), pre-existing increased serum transaminases, total or direct bilirubin greater than the upper limit of normal  |
| <b>Required Medical Information</b>  | Diagnosis of covered use (and documentation surgical intervention is not possible or practical), submission of serum transaminases, total and direct bilirubin, and ALP, pregnancy status for female patients of childbearing potential. |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       |  |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                |  |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | No   |

# ROZLYTREK (entrectinib)

## Products Affected

- ROZLYTREK

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Coadministration with moderate or strong CYP3A inducers or drugs that prolong the QTc interval  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, pregnancy status for female patients of childbearing potential. For non-small cell lung cancer, submission of test confirming presence of ROS1-positive tumor. For solid tumors, submission of evidence of a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation and attestation tumor is metastatic or surgical resection/other systemic therapies are unsatisfactory treatment options. |
| <b>Age Restrictions</b>              |   |
| <b>Prescriber Restrictions</b>       | Restricted to oncology  |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                |   |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |

# RUBRACA (rucaparib)

## Products Affected

- RUBRACA

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of deleterious BRCA mutation. For ovarian, fallopian tube, or primary peritoneal cancer, documentation of response to platinum-based chemotherapy and submission of pregnancy status for female patients of childbearing potential. For BRCA mutation-associated metastatic castration-resistant prostate cancer, confirmation patient (1) has been treated with or is not a candidate for taxane-based chemotherapy, and (2) is using a gonadotropin-releasing hormone analog or has had a bilateral orchiectomy. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to oncology and urology  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | Yes   |

# RYDAPT (midostaurin)

## Products Affected

- RYDAPT

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Coadministration with strong CYP3A inducers   |
| Required Medical Information  | Diagnosis of covered use, pregnancy status for female patients of childbearing potential. For acute myeloid leukemia, submission of test confirming presence of FLT3 mutation, attestation patient will be receiving cytarabine and daunorubicin induction and cytarabine consolidation with midostaurin. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to allergy, hematology, and oncology   |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# SAPROPTERIN

## Products Affected

- *javygtor*
- *sapropterin dihydrochloride oral packet*
- *sapropterin dihydrochloride oral tablet*

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use, submission of blood phenylalanine concentration.   |
| Age Restrictions              |  |
| Prescriber Restrictions       |  |
| Coverage Duration             | Initially 6 months, then 1 year  |
| Other Criteria                | For the first reauthorization, documentation of reduction in blood phenylalanine concentration from pre-treatment baseline is required. For each annual reauthorization, documented maintenance of a clinical benefit is required. |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

## SCEMBLIX (asciminib)

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### Products Affected

- SCEMBLIX ORAL TABLET 100 MG, 20 MG, 40 MG

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For use in patients with a T315I mutation, documentation patient has first tried and failed or become intolerant to ponatinib. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to hematology and oncology  |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |

## SECOND-GENERATION ANTIPSYCHOTICS

### Products Affected

- CAPLYTA ORAL CAPSULE 10.5 MG, 21 MG, 42 MG
- COBENFY
- COBENFY STARTER PACK
- FANAPT ORAL TABLET 1 MG, 10 MG, 12 MG, 2 MG, 4 MG, 6 MG, 8 MG
- FANAPT TITRATION PACK A
- FANAPT TITRATION PACK B ORAL TABLET
- FANAPT TITRATION PACK C ORAL TABLET
- REXULTI ORAL TABLET 0.25 MG, 0.5 MG, 1 MG, 2 MG, 3 MG, 4 MG
- SECUADO TRANSDERMAL PATCH 24 HOUR 3.8 MG/24HR, 5.7 MG/24HR, 7.6 MG/24HR

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Dementia-related psychosis. For Cobenfy only, moderate to severe renal impairment, urinary retention, gastric retention, hepatic impairment, untreated narrow-angle glaucoma.  |
| <b>Required Medical Information</b>  | Diagnosis of covered use. For schizophrenia, an indication related to bipolar disorder type I, or for Rexulti for major depressive disorder, submission of current or previous therapies used to treat the condition (see Other Criteria). For Cobenfy only, submission of estimated glomerular filtration rate with the requirement it is at least 60 mL/min, attestation patient does not have hepatic impairment.   |
| <b>Age Restrictions</b>              |  |
| <b>Prescriber Restrictions</b>       | Restricted to psychiatry   |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For initial authorization for schizophrenia or acute treatment of manic/mixed episodes of bipolar I disorder, the patient must have tried and failed to have an adequate response to or had an intolerance to aripiprazole and at least one other generic second-generation atypical antipsychotic. For initial authorization of Caplyta for depressive episodes associated with bipolar I disorder, the patient must have tried and failed to have an adequate response to or had an intolerance to at least two of the following drugs: cariprazine, lurasidone, olanzapine, or quetiapine. For Rexulti as an adjunctive therapy to antidepressants for major depressive disorder, the patient must have tried and failed to have an adequate response to or had an intolerance to aripiprazole and cariprazine or quetiapine. |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |

# SEDATIVE HYPNOTICS IN OLDER PATIENTS

## Products Affected

- *eszopiclone*
- *zaleplon*
- *zolpidem tartrate oral tablet*

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            |  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, documentation at least two of the following medications were tried and deemed ineffective or intolerable: Belsomra, doxepin tablets, ramelteon, and trazodone.                   |
| <b>Age Restrictions</b>              | PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger.   |
| <b>Prescriber Restrictions</b>       |  |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | Sedative hypnotic medications are high-risk medications in older patients due to increased risks of cognitive impairment, delirium, unsteady gait, syncope, falls, fractures, and motor vehicle accidents. |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |



# SIGNIFOR (pasireotide)

## Products Affected

- SIGNIFOR

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Severe hepatic impairment (Child-Pugh class C), uncorrected hypokalemia or hypomagnesemia  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of 24-hour urine free cortisol (UFC) level demonstrating a baseline value more than 1.5 times the upper limit of normal (50 micrograms or 145 nmol), attestation pituitary gland surgery is not an option for the patient or has not been curative, submission of ALT, aspartate aminotransferase, alkaline phosphatase, total bilirubin, and serum potassium and magnesium levels. |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to endocrinology  |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For the first reauthorization, documentation of clinically relevant response to therapy including but not limited to reduction of 24-hour UFC level is required. For each annual reauthorization, documented maintenance of a clinical benefit is required.  |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | No   |

# SIMVASTATIN 80 mg per day

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## Products Affected

- *ezetimibe-simvastatin oral tablet 10-80 mg*
- *simvastatin oral tablet 80 mg*

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, documentation that patient has been taking simvastatin 80 mg daily for 30 days or longer without adverse effects. |
| Age Restrictions              | 10 years of age or older  |
| Prescriber Restrictions       |   |
| Coverage Duration             | 1 year  |
| Other Criteria                | Not recommended as initial therapy nor for patients already taking lower doses of simvastatin whose response is inadequate.                 |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | Yes   |

# SIRTURO (bedaquiline)

## Products Affected

- SIRTURO

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Drug-sensitive tuberculosis, latent infection, extra-pulmonary tuberculosis  |
| Required Medical Information  | Diagnosis of covered use, confirmation that Sirturo will be co-administered with pretomanid and linezolid or at least 3 other drugs proven to be or at least 4 other drugs suspected to be effective against the patient's M. tuberculosis isolate and submission of susceptibility testing, if available. Alternatively, Sirturo may be used as one drug of a 3-drug regimen if the patient has a documented intolerance, a contraindication, or resistance to a fluoroquinolone or rifampin. |
| Age Restrictions              |  |
| Prescriber Restrictions       | Restricted to infectious diseases and pulmonology  |
| Coverage Duration             | 26 weeks   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

## SIVEXTRO (tedizolid)

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### Products Affected

- SIVEXTRO

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use, documentation of a culture and sensitivity showing that the suspected causative agent is susceptible to this medication. |
| Age Restrictions              |  |
| Prescriber Restrictions       | Restricted to infectious diseases  |
| Coverage Duration             | 6 days   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

## SKYCLARYS (omaveloxolone)

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### Products Affected

- SKYCLARYS

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Severe hepatic impairment (Child-Pugh class C), coadministration with moderate or strong CYP3A4 inducers   |
| Required Medical Information  | Diagnosis of covered use confirmed by genetic testing, submission of liver function testing or Child-Pugh score.   |
| Age Restrictions              | 16 years of age or older   |
| Prescriber Restrictions       | Restricted to neurology and specialists in genetic diseases  |
| Coverage Duration             | 1 year   |
| Other Criteria                | For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required. |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# SOFOSBUVIR/VELPATASVIR

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## Products Affected

- *sofosbuvir-velpatasvir*

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, laboratory confirmation of hepatitis C virus (HCV) infection and HCV genotype, attestation that patients with decompensated cirrhosis will receive concomitant ribavirin therapy unless ribavirin therapy is contraindicated. |
| Age Restrictions              |   |
| Prescriber Restrictions       |   |
| Coverage Duration             | 12 weeks  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# SOHONOS (palovarotene)

## Products Affected

- SOHONOS

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Pregnancy, coadministration with moderate or strong CYP3A4 inducers   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of test confirming presence of R206H ACVR1 mutation, pregnancy status for female patients of childbearing potential.   |
| <b>Age Restrictions</b>              | For female patients, 8 years of age or older. For male patients, 10 years of age or older.  |
| <b>Prescriber Restrictions</b>       | Restricted to orthopedics, rheumatology, and specialists in rare connective tissue diseases   |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                | For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) and attestation the patient continues to undergo regular pregnancy testing (as necessary for patients of childbearing potential) is required. |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |

# SOMAVERT (pegvisomant)

## Products Affected

- SOMAVERT

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            |   |
| <b>Required Medical Information</b>  | Diagnosis of covered use including attestation that surgery or radiation was not curative or is not an option, submission of baseline IGF-1, submission of baseline liver function testing (LFT) including bilirubin with the requirement liver transaminases are less than or equal to 3 times the upper limit of normal (ULN). If liver transaminases are greater than 3 times ULN, submission of the cause of liver dysfunction determined through a comprehensive workup.   |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to endocrinology   |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                | For the first reauthorization, submission of updated IGF-1 level demonstrating an improvement from baseline, LFT showing liver transaminases below 5 times the ULN, and attestation patient does not have signs or symptoms of liver injury (e.g., jaundice, elevated bilirubin level or bilirubinuria, fatigue, nausea, vomiting, right upper quadrant pain, ascites, unexplained edema, easy bruisability) is required. For each annual reauthorization, documented improvement/maintenance of IGF-1 level is required. |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |



# SORAFENIB

## Products Affected

- *sorafenib tosylate*

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Congenital long QT syndrome, coadministration with strong CYP3A4 inducers  |
| Required Medical Information  | Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For differentiated thyroid cancer, attestation patient is radioactive iodine-refractory or ineligible. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# STIVARGA (regorafenib)

## Products Affected

- STIVARGA

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Severe or uncontrolled hypertension, coadministration with strong CYP3A4 inhibitors or inducers  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of baseline blood pressure reading, pregnancy status for female patients of childbearing potential. For metastatic colorectal cancer, documentation of previous treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type, an anti-EGFR therapy. For gastrointestinal stromal tumor, documentation of previous treatment with imatinib and sunitinib. For hepatocellular carcinoma, documentation of previous treatment with sorafenib. |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to oncology   |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                |  |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |

# SUCRAID (sacrosidase)

## Products Affected

- SUCRAID

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, submission of laboratory-confirmed congenital sucrase-isomaltase deficiency via differential urinary disaccharide test or measurement of intestinal disaccharides following small bowel biopsy. |
| Age Restrictions              |   |
| Prescriber Restrictions       |   |
| Coverage Duration             | 1 year  |
| Other Criteria                | For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.  |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# SUNITINIB

## Products Affected

- *sunitinib malate*

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, pregnancy status for female patients of childbearing potential. For gastrointestinal stromal tumor, documentation of prior use of imatinib. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to oncology  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | Yes   |

# SUNOSI (solriamfetol)

## Products Affected

- SUNOSI ORAL TABLET 150 MG, 75 MG

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | End-stage renal disease, administration of non-selective monoamine oxidase inhibitors within 14 days of initiation, serious arrhythmias, unstable cardiovascular disease including uncontrolled hypertension  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of baseline blood pressure reading, submission of current or previous therapies used to treat the condition (see Other Criteria).  |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to neurology and sleep medicine  |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                | For initial authorization, if the patient must have tried and failed to have an adequate response to or had an intolerance/contraindication to armodafinil or modafinil. For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required. |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# TABRECTA (capmatinib)

## Products Affected

- TABRECTA

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Coadministration with moderate or strong CYP3A inducers  |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of MET exon 14 skipping mutation, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# TADALAFIL FOR BPH

## Products Affected

- *tadalafil oral tablet 2.5 mg, 5 mg*

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Erectile dysfunction indication (see Other Criteria), severe hepatic impairment (Child-Pugh class C), severe renal impairment  |
| <b>Required Medical Information</b>  | Diagnosis of benign prostatic hyperplasia (BPH), submission of creatinine clearance (or serum creatinine, actual body weight, and height to calculate estimated creatinine clearance).   |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to urology  |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required. This product will not be approved for erectile dysfunction as this use is currently excluded from coverage under Medicare Part D. |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | No   |

# TAFAMIDIS

## Products Affected

- VYNDAMAX
- VYNDAQEL

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            |  |
| <b>Required Medical Information</b>  | Diagnosis of transthyretin amyloid cardiomyopathy (ATTRwt or ATTRm) confirmed by one of the following: (1) presence of amyloid deposits on cardiac biopsy, (2) presence of transthyretin precursor protein confirmed on immunohistochemical analysis, (3) technetium 99-labeled nuclear scintigraphy or single-photon emission computer tomography (SPECT), or (4) a TTR genetic mutation plus cardiac involvement defined as thickening of the interseptal ventricular wall. In addition, patients should also have documentation of history of heart failure, with at least one prior hospitalization for heart failure or clinical evidence of heart failure with signs or symptoms of volume overload requiring treatment with a diuretic for improvement. |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to cardiology   |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.   |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | No   |



# TAGRISSO (osimertinib)

## Products Affected

- TAGRISSO

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of EGFR exon 19 deletions, exon 21 L858R mutations, or T790M mutations, pregnancy status for female patients of childbearing potential. For EGFR T790M mutation-positive NSCLC, submission of previous EGFR tyrosine kinase inhibitor therapy used for indication. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to oncology  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# TALZENNA (talazoparib)

## Products Affected

- TALZENNA ORAL CAPSULE 0.1 MG, 0.25 MG, 0.35 MG, 0.5 MG, 0.75 MG, 1 MG

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use, pregnancy status for female patients of childbearing potential. For breast cancer, submission of test results confirming germline BRCA mutation-positive, human epidermal growth factor receptor 2 (HER2) negative disease. For prostate cancer, submission of test results confirming HRR gene-mutated disease, confirmation talazoparib will be used in combination with enzalutamide. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# TASIMELTEON

## Products Affected

- *tasimelteon*

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Severe hepatic impairment, coadministration with strong CYP1A2 inhibitors or CYP3A4 inducers  |
| <b>Required Medical Information</b>  | Diagnosis of covered use. For non-24-hour sleep-wake disorder, attestation patient is totally blind. For Smith-Magenis Syndrome, documentation of genetic testing results confirming chromosome 17p11.2 deletion. |
| <b>Age Restrictions</b>              |   |
| <b>Prescriber Restrictions</b>       | Restricted to neurology and sleep medicine  |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                | For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.  |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |

# TAVNEOS (avacopan)

## Products Affected

- TAVNEOS

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Coadministration with moderate or strong CYP3A4 inducers, active serious infection, chronic active hepatitis B, untreated hepatitis C, uncontrolled autoimmune hepatitis, cirrhosis  |
| <b>Required Medical Information</b>  | Diagnosis of covered use (granulomatosis with polyangiitis or microscopic polyangiitis variants of anti-neutrophil cytoplasmic antibody [ANCA]-associated vasculitis), submission of HBV serology testing, attestation patient is using rituximab, cyclophosphamide/azathioprine, or another compendium-supported therapy for the treatment of ANCA-associated vasculitis, along with glucocorticoids.             |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to immunology, nephrology, pulmonology, and rheumatology  |
| <b>Coverage Duration</b>             | Initially 6 months, then 1 year  |
| <b>Other Criteria</b>                | For the first reauthorization, documentation of clinically relevant response to therapy, including but not limited to disease remission defined using changes in Birmingham Vasculitis Activity Score, a documented reduction in maintenance glucocorticoid dose, or improved or sustained renal function, is required. For each annual reauthorization, documented maintenance of a clinical benefit is required. |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | No   |

# TAZVERIK (tazemetostat)

## Products Affected

- TAZVERIK

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Coadministration with moderate or strong CYP3A4 inducers   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For relapsed/refractory follicular lymphoma, documentation (1) of test confirming presence of EZH2 mutation and treatment with at least two prior systemic therapies, or (2) patient has no satisfactory alternative treatment option. |
| <b>Age Restrictions</b>              | 16 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to hematology and oncology  |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                |  |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |

# TEPMETKO (tepotinib)

## Products Affected

- TEPMETKO

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of MET exon 14 skipping mutation, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# TERIPARATIDE

## Products Affected

- *teriparatide subcutaneous solution pen-injector 560 mcg/2.24ml*

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Pre-existing hypercalcemia, underlying hypercalcemic disorder (such as primary hyperparathyroidism), patients with an increased risk of osteosarcoma (such as those with Paget's disease)  |
| <b>Required Medical Information</b> | Diagnosis of covered use where "high risk for fracture" is defined as documentation of (1) a history of fracture of the hip or vertebra regardless of bone mineral density (BMD), or (2) a history of fracture of the proximal humerus, pelvis, or distal forearm and T-score between -1.0 and -2.5, or (3) T-score less than or equal to -2.5 at the total hip, femoral neck, spine, or distal third of the radius, or (4) T-score between -1.0 and -2.5 at the total hip, femoral neck, spine, or distal third of the radius, and (a) a 10-year probability of hip fracture as assessed by FRAX score of at least 3%, or (b) a 10-year probability of a major osteoporosis-related fracture as assessed by FRAX score of at least 20%, submission of baseline serum calcium, postmenopausal status, current or previous therapies used to treat the condition (see Other Criteria), number of total months of all prior use of parathyroid hormone analogs and parathyroid hormone related peptides. |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 2 years unless patient is at high risk for fracture after 2 years of therapy (see Other Criteria)  |
| <b>Other Criteria</b>               | For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance/contraindication to at least one bisphosphonate. Therapeutic failure is defined as either a fracture or a decrease in BMD while using a bisphosphonate for at least 3 months. Use of parathyroid hormone analogs and/or parathyroid hormone related peptides for more than 2 years during a patient's lifetime is generally not recommended. For annual reauthorization beyond 2 years, submission of updated serum calcium since initial authorization and evidence the patient remains at high risk for fracture as defined in the Required Medical Information section is required.   |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |
| <b>Part B Prerequisite</b>          | No   |

| PA Criteria                   | Criteria Details |
|-------------------------------|------------------|
| Prerequisite Therapy Required | Yes              |



# TESTOSTERONE REPLACEMENT PRODUCTS

## Products Affected

- testosterone transdermal gel 10 mg/act (2%), 12.5 mg/act (1%), 20.25 mg/1.25gm (1.62%), 20.25 mg/act (1.62%), 25 mg/2.5gm (1%), 40.5 mg/2.5gm (1.62%), 50 mg/5gm (1%)
- testosterone transdermal solution

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | History of breast cancer  |
| Required Medical Information  | Diagnosis of covered use, submission of serum testosterone level, attestation that patient has been evaluated for the presence of prostate cancer prior to initiation of therapy. |
| Age Restrictions              |   |
| Prescriber Restrictions       |   |
| Coverage Duration             | 1 year  |
| Other Criteria                | For each annual reauthorization, submission of increased serum testosterone level (or maintenance of a previous increase in serum testosterone level) is required.                |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# TIBSOVO (ivosidenib)

## Products Affected

- TIBSOVO

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Coadministration with strong CYP3A inducers  |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of IDH1 mutation. For cholangiocarcinoma, documentation of at least one previous therapy that was tried and failed. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to hematology and oncology  |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |

# TOLVAPTAN (ADPKD)

## Products Affected

- *tolvaptan oral tablet 15 mg, 30 mg*
- *tolvaptan oral tablet therapy pack 15 mg, 30 & 15 mg, 45 & 15 mg, 60 & 30 mg, 90 & 30 mg*

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | History of signs or symptoms of significant liver impairment or injury (not including uncomplicated polycystic liver disease), uncorrected abnormal blood sodium concentrations, inability to sense or respond to thirst, hypovolemia, uncorrected urinary outflow obstruction, anuria, coadministration with strong CYP3A inhibitors or inducers or desmopressin                                     |
| <b>Required Medical Information</b>  | Diagnosis of covered use where rapidly progressing autosomal dominant polycystic kidney disease is defined as positive identification of kidney cysts on imaging plus (1) Mayo Imaging Classification 1C, 1D, or 1E, or (2) historical eGFR decline of at least 3 mL/min/1.73 m <sup>2</sup> year over a 4-year period, or (3) PROPKD score greater than 6, submission of serum sodium concentration. |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to nephrology  |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                | For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.  |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |

# TOLVAPTAN (HYPONATREMIA)

## Products Affected

- *tolvaptan (hyponatremia)*

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Underlying liver disease, need to raise serum sodium acutely, inability to sense or respond to thirst, hypovolemia, anuria, coadministration with strong CYP3A inhibitors or inducers or desmopressin  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of evidence of clinically significant hyponatremia, defined as (1) serum sodium less than 125 mEq/L, or (2) serum sodium less than 135 mEq/L that is symptomatic and has resisted correction with fluid restriction.  |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       |  |
| <b>Coverage Duration</b>             | 30 days (see Other Criteria)   |
| <b>Other Criteria</b>                | Treatment should be initiated in a setting where serum sodium can be monitored closely. Treatment is limited to 30 days to prevent liver injury. This formulation of tolvaptan will not be approved for autosomal dominant polycystic kidney disease (ADPKD) as it is not indicated for ADPKD and the tolvaptan formulation approved for ADPKD has a mandatory REMS program, making it only available through a restricted distribution program. |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | No   |

# TOPICAL RETINOIDS

## Products Affected

- *adapalene external cream*
- *adapalene external gel 0.3 %*
- *tazarotene external cream*
- *tazarotene external gel*
- *tretinoin external cream*
- *tretinoin external gel 0.01 %, 0.025 %*

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Cosmetic use (e.g., hyperpigmentation, keloids, photoaging, wrinkles)   |
| <b>Required Medical Information</b>  | For adapalene or tretinoin, diagnosis of acne vulgaris. For tazarotene, diagnosis of acne vulgaris or plaque psoriasis.   |
| <b>Age Restrictions</b>              |   |
| <b>Prescriber Restrictions</b>       |   |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                | For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of improvement previously achieved) is required. Drugs in this policy will not be approved for cosmetic uses as these uses are currently excluded from coverage under Medicare Part D. |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |

# TRUQAP (capivasertib)

## Products Affected

- TRUQAP ORAL TABLET
- TRUQAP ORAL TABLET THERAPY PACK

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Coadministration with moderate or strong CYP3A4 inducers   |
| Required Medical Information  | Diagnosis of covered use, submission of genetic tumor testing confirming that the primary tumor type is HR-positive, HER2-negative and has at least one PIK3CA, AKT1, and/or PTEN mutation, submission of pregnancy status for female patients of childbearing potential, attestation patient has (1) progressed on at least one endocrine-based regimen in the metastatic setting, or (2) has recurrent disease on or within 12 months of completing adjuvant therapy, attestation drug will be given with fulvestrant. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |

# TUKYSA (tucatinib)

## Products Affected

- TUKYSA ORAL TABLET 150 MG, 50 MG

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Pregnancy, coadministration with strong CYP3A inducers or moderate CYP2C8 inducers   |
| Required Medical Information  | Diagnosis of covered use, submission of genetic tumor testing confirming that the primary tumor type is HER2-positive, pregnancy status for female patients of childbearing potential. For breast cancer, submission of previous anti-HER2-directed therapy. For metastatic colon cancer, documentation tumor is RAS wild-type, attestation patient experienced progression following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |

# TURALIO (pexidartinib)

## Products Affected

- TURALIO ORAL CAPSULE 125 MG

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Active liver or biliary tract disease (including increased ALP), pre-existing increased serum transaminases, total or direct bilirubin greater than the upper limit of normal, coadministration with other hepatotoxic medications, strong CYP3A inducers, or proton pump inhibitors                            |
| Required Medical Information  | Diagnosis of covered use (and documentation surgical intervention is not possible or practical), documentation of patient's severe morbidity or functional limitations, submission of serum transaminases, total and direct bilirubin, and ALP, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       |   |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |



# UZEDY (risperidone)

## Products Affected

- UZEDY

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Dementia-related psychosis  |
| Required Medical Information  | Diagnosis of covered use, submission of current or previous therapies used to treat the condition (see Other Criteria).   |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       |   |
| Coverage Duration             | 1 year  |
| Other Criteria                | For initial authorization, the patient must have had a documented trial of or had an intolerance/contraindication to generic intramuscular risperidone. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | Yes   |

# VALCHLOR (mechlorethamine)

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## Products Affected

- VALCHLOR

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Use as initial therapy  |
| Required Medical Information  | Diagnosis of covered use, submission of previous skin-directed therapy. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to dermatology and oncology                                  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# VANFLYTA (quizartinib)

## Products Affected

- VANFLYTA

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Requests for maintenance monotherapy after allogeneic hematopoietic stem cell transplant, uncorrected hypokalemia or hypomagnesemia, long QT syndrome, QTcF interval greater than 450 msec at treatment initiation, coadministration with moderate or strong CYP3A inducers   |
| <b>Required Medical Information</b>  | Diagnosis of covered use including submission of test confirming presence of FLT3 internal tandem duplication-positive mutation, submission of QTcF interval, baseline serum potassium and magnesium levels, and pregnancy status for female patients of childbearing potential, attestation patient does not have history of ventricular arrhythmias or torsades de pointes. |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to hematology and oncology   |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                |   |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |

# VANRAFIA (atrasentan)

## Products Affected

- VANRAFIA

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Pregnancy, severe hepatic impairment, coadministration with moderate or strong CYP3A inducers  |
| <b>Required Medical Information</b>  | Diagnosis of primary IgA nephropathy confirmed by biopsy, submission of 24-hour urine protein of at least 0.5 g/day or 24-hour urine protein-to-creatinine ratio (UPCR) of at least 0.8 g/g, liver function testing or Child-Pugh score, pregnancy status for female patients of childbearing potential, submission of current or previous therapies used to treat the condition (see Other Criteria).   |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to immunology and nephrology  |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For initial authorization, the patient must be currently using (or have a contraindication to the use of) a maximally-tolerated dose of an ACE inhibitor or ARB and tried and failed to have an adequate response to or had an intolerance to at least one SGLT-2 inhibitor (e.g., dapagliflozin, empagliflozin). For each annual reauthorization, documentation of clinically relevant response to therapy, including either stabilization or improvement of UPCR or a reduction in 24-hour urine protein from baseline, is required. |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |

# VENCLEXTA (venetoclax)

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## Products Affected

- VENCLEXTA ORAL TABLET 10 MG, 100 MG, 50 MG
- VENCLEXTA STARTING PACK

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Coadministration with moderate or strong CYP3A inducers. For CLL/SLL, coadministration with strong CYP3A inhibitors at treatment initiation and initial dosage titration. |
| Required Medical Information  | Diagnosis of covered use, pregnancy status for female patients of childbearing potential.   |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to hematology and oncology   |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# VEOZAH (fezolinetant)

## Products Affected

- VEOZAH

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Coadministration with CYP1A2 inhibitors, severe renal impairment or end-stage renal disease, known cirrhosis, any aminotransferase or total bilirubin at or above 2 times the upper limit of normal  |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of estimated glomerular filtration rate, liver function testing, current or previous therapies used to treat the condition (see Other Criteria).  |
| <b>Age Restrictions</b>              |  |
| <b>Prescriber Restrictions</b>       |  |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance to at least two prior systemic hormone therapies or FDA-approved or compendia-supported non-hormonal therapies (e.g., SSRI, SNRI, clonidine, gabapentin, etc.) for the treatment of vasomotor symptoms due to menopause. The drugs tried must come from different medication classes. For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required. |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |

# VERQUVO (vericiguat)

## Products Affected

- VERQUVO ORAL TABLET 10 MG, 2.5 MG, 5 MG

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Pregnancy, concomitant use of another soluble guanylate cyclase (sGC) stimulator or a phosphodiesterase-5 (PDE-5) inhibitor  |
| <b>Required Medical Information</b>  | Diagnosis, including either hospitalization for heart failure with reduced ejection fraction (HFrEF) within the previous 6 months or outpatient IV diuretic use within the previous 3 months, submission of left ventricular ejection fraction with the requirement it is less than 45%, pregnancy status for female patients of childbearing potential, submission of current or previous therapies used to treat the condition (see Other Criteria).   |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to cardiology   |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For initial authorization, the patient's regimen for HFrEF must be submitted and must include (1) an angiotensin-converting enzyme (ACE) inhibitor, angiotensin II receptor blocker (ARB), or sacubitril/valsartan, and (2) a beta-blocker (BB), and (3) a mineralocorticoid receptor antagonist, each at maximally-tolerated doses. Using the recommended dose of each therapeutic component to treat HFrEF is required. If the doses of any of these three components have not been optimized to the recommended dose to treat HFrEF or any of these three therapies are not currently being used, prescriber is required to submit documentation as to why (e.g., intolerances, physiologic parameters, contraindications, etc.). If the patient is using a BB not indicated for HFrEF, the patient will be required to switch to one of the three FDA-approved BBs for HFrEF (bisoprolol, carvedilol, or metoprolol succinate). For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required. |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | Yes  |

# VERZENIO (abemaciclib)

## Products Affected

- VERZENIO

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Coadministration with moderate or strong CYP3A4 inducers or ketoconazole  |
| Required Medical Information  | Diagnosis of covered use, submission of genetic tumor testing confirming that the primary tumor type is HR-positive, HER2-negative, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to oncology  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |



# VIBERZI (eluxadoline)

## Products Affected

- VIBERZI

| PA Criteria                          | Criteria Details   |
|--------------------------------------|--|
| <b>Exclusion Criteria</b>            | Prior cholecystectomy, known or suspected biliary duct obstruction, known or suspected sphincter of Oddi disease or dysfunction, alcoholism, alcohol abuse, alcohol addiction, or patients who drink more than 3 alcoholic beverages/day, history of pancreatitis, structural diseases of pancreas including known or suspected pancreatic duct obstruction, severe hepatic impairment (Child-Pugh class C), severe constipation or sequelae from constipation, known or suspected mechanical gastrointestinal obstruction |
| <b>Required Medical Information</b>  | Diagnosis of covered use.  |
| <b>Age Restrictions</b>              | 18 years of age or older   |
| <b>Prescriber Restrictions</b>       | Restricted to gastroenterology   |
| <b>Coverage Duration</b>             | 1 year   |
| <b>Other Criteria</b>                | For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.   |
| <b>Indications</b>                   | All FDA-approved Indications.  |
| <b>Off Label Uses</b>                |  |
| <b>Part B Prerequisite</b>           | No   |
| <b>Prerequisite Therapy Required</b> | No   |

# VIJOICE (alpelisib)

## Products Affected

- VIJOICE ORAL PACKET
- VIJOICE ORAL TABLET THERAPY PACK 125 MG, 200 & 50 MG, 50 MG

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Coadministration with strong CYP3A4 inducers   |
| Required Medical Information  | Diagnosis of covered use including at least one target lesion on imaging with requesting provider attestation patient has severe or life-threatening disease, submission of test confirming presence of mutation in PIK3CA gene, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              |  |
| Prescriber Restrictions       | Restricted to specialists in genetic diseases or inborn errors of metabolism   |
| Coverage Duration             | Initially 6 months, then 1 year  |
| Other Criteria                | For each reauthorization, submission of objective documentation of a symptomatic or clinical benefit (e.g., reductions in target lesion size, pain, vascular malformations, limb enlargements, etc.), or maintenance of improvement previously achieved, is required.                            |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# VITRAKVI (larotrectinib)

## Products Affected

- VITRAKVI ORAL CAPSULE 100 MG, 25 MG
- VITRAKVI ORAL SOLUTION

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, submission of evidence of a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, attestation tumor is metastatic or surgical resection and other systemic therapies are unsatisfactory treatment options, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              |   |
| Prescriber Restrictions       | Restricted to oncology  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# VIVJOA (oteseconazole)

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## Products Affected

- VIVJOA

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Women of reproductive potential  |
| Required Medical Information  | Diagnosis of covered use, including attestation patient has had at least three episodes of vulvovaginal candidiasis in the previous 12 months, attestation patient is either (1) postmenopausal, or (2) infertile. |
| Age Restrictions              |  |
| Prescriber Restrictions       |  |
| Coverage Duration             | 12 weeks   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# VIZIMPRO (dacomitinib)

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## Products Affected

- VIZIMPRO ORAL TABLET 15 MG, 30 MG, 45 MG

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Coadministration with a proton pump inhibitor   |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of EGFR exon 19 deletions or exon 21 L858R substitution mutations, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to oncology  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# VONJO (pacritinib)

## Products Affected

- VONJO

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            | Moderate or severe hepatic impairment (Child-Pugh class B or C), estimated glomerular filtration rate (eGFR) less than 30 mL/min, QTc interval greater than 480 msec at baseline, uncorrected hypokalemia, coadministration with strong CYP3A4 inducers or strong CYP3A4 inhibitors |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of platelet count, serum potassium level, eGFR, and QTc interval, Child-Pugh score, documentation from a physical exam patient has splenomegaly.   |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to hematology and oncology   |
| <b>Coverage Duration</b>             | 1 year  |
| <b>Other Criteria</b>                |   |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | No  |

# VOQUEZNA (vonoprazan)

## Products Affected

- VOQUEZNA ORAL TABLET 10 MG, 20 MG

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use. For erosive esophagitis and non-erosive gastroesophageal reflux disease (GERD), submission of current or previous therapies used to treat the condition (see Other Criteria). For Helicobacter pylori infection only, attestation patient will be administering with amoxicillin or a combination of amoxicillin and clarithromycin.   |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       |  |
| Coverage Duration             | Up to 32 weeks based on covered use (see Other Criteria)   |
| Other Criteria                | For initial authorization for erosive esophagitis and non-erosive GERD, the patient must have tried and failed to have an adequate response to two different proton pump inhibitors or have contraindications to the proton pump inhibitor class. For non-erosive GERD, the initial coverage duration will be 4 weeks, with the option to reauthorize for an additional 20 weeks (for a total of 24 weeks of therapy per 365 days) if the provider attests to medical need. For H. pylori infection, a maximum of one 14-day course of vonoprazan will be approved. For all other indications, a maximum of one 32-week course of vonoprazan will be allowed per 365 days. |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |

# VORANIGO (vorasidenib)

## Products Affected

- VORANIGO ORAL TABLET 10 MG, 40 MG

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of IDH1 or IDH2 mutation, pregnancy status for female patients of childbearing potential, attestation patient has had at least one prior surgery (biopsy, sub-total resection, or gross total resection). |
| Age Restrictions              | 12 years of age or older   |
| Prescriber Restrictions       | Restricted to oncology   |
| Coverage Duration             | 6 months   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |



# VOWST (fecal microbiota spores, live-brpk) EGWP

## Products Affected

- VOWST

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use with the requirement patient is being treated after at least 2 recurrent (3 total) Clostridioides difficile infections (confirmation of pathogen with stool test or other confirmatory test), submission of time of last planned dose of antibiotic for latest recurrent C. difficile infection and attestation patient will be using a bowel cleanse the evening prior to starting Vowst. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       |   |
| Coverage Duration             | 1 course (3 days)   |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# VOYDEYA (danicopan) EGWP

## Products Affected

- VOYDEYA ORAL TABLET
- VOYDEYA ORAL TABLET THERAPY PACK

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, documentation patient has clinically significant extravascular hemolysis, defined as a hemoglobin level less than or equal to 9.5 g/dL and an absolute reticulocyte count greater than or equal to $120 \times 10^9/L$ after having used a complement C5 inhibitor at a stable dose (see Other Criteria).   |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to hematology  |
| Coverage Duration             | Initially 6 months, then 1 year   |
| Other Criteria                | PA applies to all. For approval, the patient must also be using eculizumab or ravulizumab. Danicopan has not been shown to be effective as monotherapy and should only be prescribed as an add-on to complement C5 inhibitor therapy. Continuation of therapy requests require confirmation that the patient has demonstrated a clinical improvement (or maintenance of improvement once achieved) from baseline. |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | Yes   |

# WEGOVY (semaglutide)

## Products Affected

- WEGOVY SUBCUTANEOUS SOLUTION AUTO-INJECTOR 0.25 MG/0.5ML, 0.5 MG/0.5ML, 1 MG/0.5ML, 1.7 MG/0.75ML, 2.4 MG/0.75ML

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Weight management indication (see Other Criteria), personal or family history of medullary thyroid carcinoma, Multiple Endocrine Neoplasia syndrome type 2  |
| <b>Required Medical Information</b> | To reduce the risk of major adverse cardiovascular events (MACE), documentation the patient has "established cardiovascular disease" defined as presence of at least one of the following: (1) prior myocardial infarction, (2) prior stroke, and/or (3) symptomatic peripheral arterial disease, further defined as presence of at least one of the following: (a) intermittent claudication with an ankle-brachial index less than 0.85 (at rest), or (b) a peripheral arterial revascularization procedure, or (c) an amputation due to atherosclerotic disease, submission of body mass index (BMI) with the requirement it is greater than or equal to 25 kg/m <sup>2</sup> , attestation patient is not using semaglutide for diabetes mellitus, does not have a personal or family history of medullary thyroid carcinoma or a diagnosis of Multiple Endocrine Neoplasia syndrome type 2, and is not receiving another GLP-1 agonist for the treatment of any condition, submission of a medication regimen the patient is using for the management of cardiovascular risk factors. For metabolic dysfunction-associated steatohepatitis (MASH), confirmation patient has F2 or F3 fibrosis by either liver biopsy, magnetic resonance elastography, or vibration-controlled elastography, submission of liver function testing or Child-Pugh score. |
| <b>Age Restrictions</b>             | 18 years of age or older  |
| <b>Prescriber Restrictions</b>      | Restricted to cardiology, gastroenterology, and hepatology  |
| <b>Coverage Duration</b>            | Initially 32 weeks, then 1 year   |
| <b>Other Criteria</b>               | For each reauthorization for MACE, submission of an updated established cardiovascular disease regimen to follow requirements as outlined in the Required Medical Information criteria is required. For the first reauthorization for MASH, documentation confirming resolution of MASH or improvement or stabilization of fibrosis stage from baseline, as assessed by biopsy or noninvasive testing, is required. For each annual reauthorization for MASH, documented maintenance of a clinical benefit is required. This product will not be approved for weight management as this use is currently excluded from coverage under Medicare Part D.  |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

| PA Criteria                   | Criteria Details |
|-------------------------------|------------------|
| Part B Prerequisite           | No               |
| Prerequisite Therapy Required | No               |

# WELIREG (belzutifan)

## Products Affected

- WELIREG

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For von Hippel-Lindau (VHL) disease, confirmation of a germline VHL alteration and attestation patient does not require immediate surgery. For advanced renal cell carcinoma, confirmation patient was previously treated with a programmed death receptor-1 or programmed death-ligand 1 inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor. |
| Age Restrictions              | 12 years of age or older  |
| Prescriber Restrictions       | Restricted to oncology  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | Yes   |

# WINREVAIR (sotatercept-csrk)

## Products Affected

- WINREVAIR SUBCUTANEOUS KIT 2 X 45 MG, 2 X 60 MG, 45 MG, 60 MG

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Platelet count below $50 \times 10^9/L$ , pregnancy   |
| Required Medical Information  | Diagnosis of covered use confirmed by right heart catheterization, submission of mean pulmonary arterial pressure greater than 20 mm Hg at rest, pulmonary arterial wedge pressure less than or equal to 15 mm Hg, pulmonary vascular resistance greater than 2 Woods units, New York Heart Association functional class with the requirement the patient falls into Class II, III, or IV, attestation patient is WHO Group 1, submission of baseline platelet count, current or previous therapies used to treat the condition (see Other Criteria), and pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to cardiology and pulmonology  |
| Coverage Duration             | Initially 6 months, then 1 year   |
| Other Criteria                | For initial authorization, the patient's drug regimen must be submitted and must include at minimum (1) a nitric oxide pathway mediator and (2) an endothelin receptor antagonist, with or without a prostacyclin pathway agonist. If dual or triple therapy is not currently being used, prescriber is required to submit documentation as to why (e.g., intolerances, physiologic parameters, contraindications, etc.). For each reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | Yes   |

## XALKORI (crizotinib)

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### Products Affected

- XALKORI

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Congenital long QT syndrome, coadministration with strong CYP3A inducers   |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming tumor is ALK or ROS1-positive, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | For ALK-positive systemic anaplastic large cell lymphoma only, 1 year of age to 21 years of age  |
| Prescriber Restrictions       | Restricted to hematology and oncology  |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# XDEMVY (lotilaner)

## Products Affected

- XDEMVY

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use including documentation of presence of mites upon examination of eyelashes by light microscopy or presence of collarettes on slit lamp examination, documentation of at least mild erythema of lid margin. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to ophthalmology and optometry   |
| Coverage Duration             | 6 weeks   |
| Other Criteria                | The safety and efficacy of retreating with additional courses has not been fully described. For this reason, only one 6-week treatment course will be allowed every 365 days.   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |



## XERMELO (telotristat)

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### Products Affected

- XERMELO

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use, documentation patient has been on at least 12 weeks of prior somatostatin analog therapy.  |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       |  |
| Coverage Duration             | 1 year   |
| Other Criteria                | For each reauthorization, documentation patient remains on somatostatin analog therapy (unless contraindicated) and confirmation that the patient has not experienced episodes of severe constipation is required. |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |

# XIFAXAN (rifaximin)

## Products Affected

- XIFAXAN ORAL TABLET 550 MG

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            |   |
| <b>Required Medical Information</b>  | Diagnosis of covered use, submission of current and previous therapies used to treat the condition (see Other Criteria). For diarrhea-predominant irritable bowel disease (IBS-D), documentation of the number of previous 14-day courses of rifaximin used during the patient's lifetime. For small intestinal bacterial overgrowth (SIBO), documentation of positive results on a carbohydrate breath test and the number of previous 14-day courses of rifaximin used during the previous 365 days, including the date ranges of those courses of therapy.   |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to gastroenterology and hepatology   |
| <b>Coverage Duration</b>             | For HE, 1 year. For IBS-D and SIBO, 14 days.  |
| <b>Other Criteria</b>                | For initial authorization for hepatic encephalopathy (HE), the patient must have tried and failed to have an adequate response to or had an intolerance/contraindication to lactulose. For authorization for IBS-D, the patient must have tried and failed to have an adequate response to at least two of the following classes of medications: (1) antidiarrheals (e.g., loperamide), or (2) antispasmodics (e.g., dicyclomine), or (3) tricyclic antidepressants (e.g., nortriptyline). For initial authorization for SIBO, the patient must have tried and failed to have an adequate response to or had an intolerance to at least two other medications with evidence of efficacy including amoxicillin-clavulanate, ciprofloxacin, metronidazole, sulfamethoxazole/trimethoprim, and tetracycline. For IBS-D, a maximum of three 14-day courses per patient's lifetime will be approved. For SIBO, a maximum of two 14-day courses per 365 days can be approved. |
| <b>Indications</b>                   | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# XOLAIR (omalizumab)

## Products Affected

- XOLAIR

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | Weight greater than 150 kg, other forms of urticaria that are not chronic spontaneous urticaria (CSU)  |
| Required Medical Information | Diagnosis of covered use, submission of pre-treatment weight. For asthma, chronic rhinosinusitis with nasal polyps (CRSwNP), and CSU, submission of current and previous therapies used to treat the condition (see Other Criteria). For asthma, (1) documentation patient has a pre-bronchodilator FEV1 less than 80 percent predicted or less than 90% in children, and, (2) submission of pre-treatment serum IgE level between 30 and 700 IU/mL in patients 12 years of age and older, and (3) positive skin test result or demonstrated in vitro reactivity (RAST test) to a perennial aeroallergen. For CRSwNP, (1) documentation of evidence of nasal polyps, and (2) attestation that patient has symptomatic nasal congestion, and (3) submission of pre-treatment serum IgE level with a requirement it must be at least 30 IU/mL. For food allergy, (1) documentation of at least one IgE-mediated food allergy proven by skin prick test and positive IgE testing, and (2) submission of pre-treatment serum IgE level with a requirement it must be at least 30 IU/mL, and (3) attestation patient will continue to follow a food allergen-avoidance diet, and (4) attestation patient is not using other immunotherapy (e.g., Palforzia) for indication. |
| Age Restrictions             |  |
| Prescriber Restrictions      | Restricted to allergy, dermatology, immunology, otolaryngology/otorhinolaryngology, and pulmonology  |
| Coverage Duration            | Initially 6 months, then 1 year  |

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Other Criteria                | <p>For initial authorization for asthma, patient must be on a drug regimen as recommended by GINA guidelines prior to the use of biologic medications, consisting of, at a minimum, a maximally-tolerated dose of inhaled corticosteroid (ICS), a long-acting beta-agonist (LABA), and a long-acting antimuscarinic antagonist (LAMA), and the provider must attest this therapy will be continued after starting omalizumab. For initial authorization for CRSwNP, patient must have tried an intranasal corticosteroid for at least two months (and provider must attest this will be continued after starting omalizumab), have a contraindication to intranasal corticosteroids, or documentation must be submitted as to why this therapy is not otherwise advisable. For initial authorization for CSU, patient must have tried and continued to experience severe itching and hives despite a trial of at least 30 days of an oral antihistamine. For each reauthorization for asthma, confirmation patient is still using triple ICS-LABA-LAMA inhaler therapy and documentation of a clinical benefit (reduction from baseline in rate of annual exacerbations or severe exacerbations, systemic corticosteroid dose, or asthma symptom score, improvement in FEV1) or maintenance of a benefit previously achieved is required. For each reauthorization for CRSwNP, confirmation patient is still using an intranasal corticosteroid and documentation of a clinical benefit (reduction from baseline in nasal congestion, nasal polyp score or systemic corticosteroid dose) or maintenance of a benefit previously achieved is required. For each reauthorization for CSU, documentation of a clinical benefit (reduction from baseline in itch severity or hive count) or maintenance of a benefit previously achieved is required. For each reauthorization for food allergy, attestation patient has medical necessity and is not using other immunotherapies for food allergy is required. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.</p> |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | Yes   |

# XOSPATA (gilteritinib)

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## Products Affected

- XOSPATA

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Uncorrected hypokalemia or hypomagnesemia, coadministration with dual strong CYP3A/P-glycoprotein inducers  |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of FLT3 mutation, baseline serum potassium and magnesium levels, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to hematology and oncology   |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

# XPOVIO (selinexor)

## Products Affected

- XPOVIO (100 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 50 MG
- XPOVIO (40 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 10 MG, 40 MG
- XPOVIO (40 MG TWICE WEEKLY) ORAL TABLET THERAPY PACK 40 MG
- XPOVIO (60 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 60 MG
- XPOVIO (60 MG TWICE WEEKLY)
- XPOVIO (80 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 40 MG
- XPOVIO (80 MG TWICE WEEKLY)

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For multiple myeloma in combination with bortezomib and dexamethasone, documented failure of at least one previous therapy. For relapsed or refractory multiple myeloma, documented failure of at least four previous lines of systemic therapy including at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody. For relapsed or refractory diffuse large B-cell lymphoma, documented failure of at least two previous lines of systemic therapy. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to hematology and oncology  |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |

## XURIDEN (uridine triacetate)

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### Products Affected

- XURIDEN

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use, submission of baseline CBC including neutrophil count and mean corpuscular volume, baseline urine orotic acid level.                         |
| Age Restrictions              |  |
| Prescriber Restrictions       |  |
| Coverage Duration             | 1 year   |
| Other Criteria                | For each annual reauthorization, documentation of improvements or stabilization of urine orotic acid level, neutrophil count, and mean corpuscular volume is required. |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | No   |

# ZEJULA (niraparib)

## Products Affected

- ZEJULA ORAL TABLET

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            |  |
| Required Medical Information  | Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential, documentation of response to platinum-based chemotherapy. For germline BRCA-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, submission of test confirming presence of deleterious BRCA mutation. |
| Age Restrictions              | 18 years of age or older   |
| Prescriber Restrictions       | Restricted to oncology   |
| Coverage Duration             | 1 year   |
| Other Criteria                |  |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |



# ZILBRYSQ (zilucoplan)

## Products Affected

- ZILBRYSQ

| PA Criteria                          | Criteria Details  |
|--------------------------------------|---|
| <b>Exclusion Criteria</b>            |   |
| <b>Required Medical Information</b>  | Diagnosis of covered use including confirmation via a history of abnormal neuromuscular transmission tests or improvement with acetylcholinesterase inhibitors and a positive serological test for AChR-Ab, submission of MGFA classification with a requirement the patient has class II-IV myasthenia gravis and baseline MG-ADL score with a requirement the score is at least 6, attestation patient will not concurrently use rituximab or eculizumab, submission of current or previous therapies used to treat the condition (see Other Criteria), attestation patient has received meningococcal vaccination against subgroups A, B, C, W, and Y and does not have an unresolved N. meningitidis infection. |
| <b>Age Restrictions</b>              | 18 years of age or older  |
| <b>Prescriber Restrictions</b>       | Restricted to neurology   |
| <b>Coverage Duration</b>             | Initially 6 months, then 1 year   |
| <b>Other Criteria</b>                | For the initial authorization, the patient must have tried and failed to have an adequate response to at least one drug in two of the following three classes: (1) acetylcholinesterase inhibitors (e.g., pyridostigmine), or (2) corticosteroids (e.g., prednisone), or (3) non-steroidal immunosuppressive therapies (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate). For the first reauthorization, confirmation of a symptomatic or clinical improvement is required. For each annual reauthorization, confirmation of maintenance of an improvement previously achieved and attestation the patient is up to date on all vaccinations is required.   |
| <b>Indications</b>                   | All FDA-approved Indications.   |
| <b>Off Label Uses</b>                |   |
| <b>Part B Prerequisite</b>           | No  |
| <b>Prerequisite Therapy Required</b> | Yes   |

# ZORYVE (roflumilast) 0.3% CREAM

## Products Affected

- ZORYVE EXTERNAL CREAM 0.3 %

| PA Criteria                   | Criteria Details   |
|-------------------------------|--|
| Exclusion Criteria            | Requests for atopic dermatitis   |
| Required Medical Information  | Diagnosis of covered use, submission of percent body surface area affected (with a requirement BSA affected is less than or equal to 20 percent), submission of current or previous therapies used to treat the condition (see Other Criteria).  |
| Age Restrictions              | 6 years of age or older  |
| Prescriber Restrictions       | PA not required for dermatology  |
| Coverage Duration             | 1 year   |
| Other Criteria                | For initial authorization, the patient must (1) have tried and failed to have an adequate response to or had an intolerance to at least (a) one Class/Group 3 high potency or stronger topical corticosteroid, and (b) one other prescription topical agent indicated for plaque psoriasis (e.g., calcipotriene, calcitriol, tazarotene), or (2) be using a systemic medication (biologic or otherwise) to manage plaque psoriasis. For each annual reauthorization, confirmation of a symptomatic or clinical improvement or maintenance of an improvement previously achieved is required. |
| Indications                   | All FDA-approved Indications.  |
| Off Label Uses                |  |
| Part B Prerequisite           | No   |
| Prerequisite Therapy Required | Yes  |

## ZTALMY (ganaxolone)

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### Products Affected

- ZTALMY

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            |   |
| Required Medical Information  | Diagnosis of covered use confirmed by genetic testing including either (1) a CDKL5 gene that is pathogenic or likely to be pathogenic, or (2) CDKL5 deficiency. |
| Age Restrictions              |   |
| Prescriber Restrictions       | Restricted to neurology   |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

## ZURZUVAE (zuranolone)

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### Products Affected

- ZURZUVAE

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Coadministration with strong CYP3A4 inducers  |
| Required Medical Information  | Diagnosis of covered use, attestation patient is within 12 months postpartum.   |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to gynecology, obstetrics, and psychiatry  |
| Coverage Duration             | 14 days   |
| Other Criteria                | As there are no safety or efficacy data beyond one 14-day course for postpartum depression, only one 14-day course will be allowed per plan year. |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |

## ZYDELIG (idelalisib)

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### Products Affected

- ZYDELIG

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | History of toxic epidermal necrolysis with any drug, untreated active infection, coadministration with strong CYP3A inducers  |
| Required Medical Information  | Diagnosis of covered use, attestation therapy will be coadministered with rituximab, documentation of at least one previous line of systemic therapy, submission of pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to hematology and oncology   |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | Yes   |

## ZYKADIA (ceritinib)

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### Products Affected

- ZYKADIA ORAL TABLET

| PA Criteria                   | Criteria Details  |
|-------------------------------|---|
| Exclusion Criteria            | Coadministration with strong CYP3A inducers   |
| Required Medical Information  | Diagnosis of covered use, submission of test confirming presence of ALK-positive tumor, pregnancy status for female patients of childbearing potential. |
| Age Restrictions              | 18 years of age or older  |
| Prescriber Restrictions       | Restricted to oncology  |
| Coverage Duration             | 1 year  |
| Other Criteria                |   |
| Indications                   | All FDA-approved Indications.   |
| Off Label Uses                |   |
| Part B Prerequisite           | No  |
| Prerequisite Therapy Required | No  |



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