

FHCP Central Referral Department will gather clinical information to be evaluated. A clinical pharmacist with Doctor of Pharmacy degree will perform the final determination. Appeals are reviewed by a Utilization Management Physician for final determination.

- For standard requests, FHCP notifies the requesting physician, member or members' representative of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours for Medicare members after receipt of the request.
- Medications which are provided and administered by a health care professional incident to a visit are generally part B (unless self-administered greater than fifty percent of the time). If a medication is provided by a pharmacy and administered by a physician it may be Part D. Further clarification can be found at <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/determine.pdf>
- For expedited requests, FHCP notifies the requesting physician, member or member's authorized representative' representative of its determination as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the request and supporting clinical documentation. Should FHCP require additional information or documentation an additional 48 hours will be allowed to obtain the information and evaluate for a determination. Under no circumstances will an expedited request exceed 72 hours.
- Approved prior authorizations must be renewed by the member, or prescribing physician or a member's authorized representative verbally or in writing through the FHCP Central Referrals Department prior to expiration date for continued coverage.
- FHCP Central Referrals Department notifies the requesting Physician, Member or Member's representative of a favorable or an adverse Prior Authorization determination in writing. All adverse determination notices will include the appropriate instructions on how to file an Appeal.
- Once a prior authorization or step therapy request has been approved, coverage will be authorized for up to 12 months for most medications.
- When a request for a step therapy medication is denied FHCP will;
 1. Specify reason for the denial in easily understandable language.
 2. Refer to the policy, LCD, NCD or guideline upon which the decision is based.
 3. Notify the member and requesting physician they may request a copy of any criterion used to make the decision.

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4. Provide member and requesting physician with a description of appeal rights, including the right to submit written comments, documentation or other information relevant to the appeal and the timeframes for deciding appeals.
5. Provide member with a description of the expedited appeal process for urgent pre-service or urgent concurrent denials.

However, certain generic medications may be covered indefinitely at discretion of the clinical reviewer. An enrollee is not required to re-request an approval to continue using the prescription drug, as long as all of the following conditions are met:

- The member's prescribing physician continues to prescribe the drug.
- The drug continues to be considered safe and effective for treating the member's disease or medical condition.

The member continues to remain eligible under the plan.

SUMMARY OF CHANGES FROM PREVIOUS VERSION

Add MVASI, Kanjenti as preferred biosimilars, update Neulasta biosimilars Ziextenzo Nyvepria, update Rituxan biosimilars Truxima and Rituxan Hylecta, Add Step to Sinuva
Update Soliris

PROCEDURE BY MEDICATION (See Attachment 1)

PART B Prior Authorization and Step Therapy Drug List

The Centers for Medicare and Medicaid Services (CMS) has authorized Medicare Advantage (MA) plans to use step therapy for Part B drugs. Step therapy may require a Part B drug before Part B drug and Part D drug before Part B drug. Existing drug therapy must be grandfathered in, therefore, the step therapy program applies to new starts only. Medicare Advantage plans are permitted to require trial/failure of drugs supported only by off-label indication if well supported in accordance with CMS-approved compendia.

The following list of medications needs authorization through the FHCP referrals department prior to administration in the outpatient setting.

Drugs denoted as **Step Therapy (ST)** have FHCP plan specific criteria which require the use of other medications prior to the coverage of that medication.

Drugs denoted as **Prior Authorization (PA)** have CMS criteria that must be met prior to coverage; this may include NCD, LCD, CMS approved drug compendia, or general statutory requirements.

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<p>Abilify Maintena (ST)</p>	<p>Generic Name: aripiprazole injection J/Q Code: J0401</p> <hr/> <p>Step Requirements: oral aripiprazole Step J/Q Code:</p>
<p>Abraxane (PA)</p>	<p>Generic Name: paclitaxel protein bound J/Q Code: J9264</p>
<p>Actemra (ST)</p>	<p>Generic Name: tocilizumab J/Q Code: J3262</p> <hr/> <p>Step Requirements: Renflexis, Kevzara, Xeljanz, Simponi, Enbrel Step J/Q Code: Q5104, J1602</p>
<p>Acthar gel (ST)</p>	<p>Generic Name: repository corticotropin J/Q Code: J0800</p> <hr/> <p>Step Requirements: various injectable corticosteroids and disease modifying therapies (Glatopa, Gilenya, Ocrevus, Tecfidera, Aubagio, Tysabri, Avonex, Betaseron, Refbif) Step J/Q Code: J0702, J1020, J1030, J1040, J1100, J1720, J2920, J2930, J3301, J3303, J2350, J2323</p>
<p>Adcetris (PA)</p>	<p>Generic Name: brentuximab vedotin J/Q Code: J9042</p>

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Akynzeo (ST)	<p>Generic Name: netupitant/ fosnetupitant; palonosetron J/Q Code: J8655</p> <hr/> <p>Step Requirements: generic ondansetron (IV/oral), generic granisetron (oral/IV), aprepitant, fosaprepitant, Aloxi, and low-dose olanzapine (when supported by NCCN guidelines) Step J/Q Code: J1626, J2405, J2469</p>
Aldurazyme (PA)	<p>Brand Name: Aldurazyme Generic Name: laronidase J/Q Code: J1931</p>
Alimta (PA)	<p>Generic Name: premetrexed J/Q Code: J9305</p>
Aranesp (ST)	<p>Generic Name: Darbepoetin alfa J/Q Code: J0881 J0882</p> <hr/> <p>Step Requirements: Retacrit Step J/Q Code: Q5106</p>
Arzerra (PA)	<p>Generic Name: ofatumumab J/Q Code: J9303</p>

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Arzerra (ST)	<p>Generic Name: ofatumumab J/Q Code: J9302</p> <hr/> <p>Step Requirements: Ruxience (preferred), Rituxan Step J/Q Code: J9312</p>
Avastin (ST)	<p>Generic Name: bevacizumab J/Q Code: J9035</p> <hr/> <p>Step Requirements: Zirabev MVASI (preferred biosimilars) Step J/Q Code: Q5107, Q5118</p>
Bavencio (PA)	<p>Generic Name: avelumab J/Q Code: J9023</p>
Bendeka (PA)	<p>Generic Name: bendamustine J/Q Code: J9034</p>
Benlysta (ST)	<p>Generic Name: belimumab J/Q Code: J0490</p> <hr/> <p>Step Requirements: Corticosteroids, Antimalarials (Hydroxychloroquine), Non-steroidal anti- inflammatory drugs (NSAIDs), Immunosuppressants (Methotrexate, Azathioprine, Mycophenolate, Cyclosporine)</p>
Berinert (PA)	<p>Generic Name: C1 esterase inhibitor (Human) J/Q Code: J0597</p>

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Blincyto (PA)	Generic Name: blimatumomab J/Q Code: J9039
Botox (PA)	Generic Name: onabotulinum J/Q Code: j0585
Cerezyme (PA)	Generic Name: imiglucerase J/Q Code: J1786
Cinacalcet (ESRD) (PA)	Brand Name: Sensipar Generic Name: cinacalcet J/Q Code: J0604
Cinryze (ST)	Generic Name: C1 esterase inhibitor (Human) J/Q Code: J0598 Step Requirements: danazol, aminocaprioc acid, tranexamic acid Step J/Q Code:
Cresemba (ST)	Generic Name: isavuconazole J/Q Code: Step Requirements: invasive aspergillosis: voriconazole, invasive mucormycosis: Amphotericin B Step J/Q Code:

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Cuvitru (ST)	<p>Generic Name: Subcutaneous Immune Globulin J/Q Code: J1555</p> <hr/> <p>Step Requirements: Gammagard, Gammunex Step J/Q Code: J1569, J1561</p>
Cyramza (PA)	<p>Generic Name: ramucirumab J/Q Code: J9308</p>
Daptomycin (ST)	<p>Brand Name: Cubicin Generic Name: daptomycin J/Q Code: J0878</p> <hr/> <p>Step Requirements: vancomycin, linezolid, sulfamethoxazole/TMP, rifampin, clindamycin, doxycycline Step J/Q Code: J3370, J2020</p>
Darzalex IV (PA)	<p>Generic Name: daratumumab J/Q Code: J9145</p>
Doxil/Lipodox (PA)	<p>Generic Name: doxorubicin Liposomal J/Q Code: Q2050</p>
Dysport (PA)	<p>Generic Name: abobotulinum J/Q Code: j0586</p>
Elaprase (PA)	<p>Generic Name: idursulfase J/Q Code: J1743</p>
Elitek (PA)	<p>Generic Name: rasburicase J/Q Code: J2783</p>
Empliciti (PA)	<p>Generic Name: elotuzumab J/Q Code: J9176</p>

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Entyvio IV (ST)	Generic Name: vedolizumab J/Q Code: J3380 <hr/> Step Requirements: Renflexis Step J/Q Code: Q5104
Epogen (ST)	Generic Name: Epoetin alfa J/Q Code: J0885, Q4081 Step Requirements: Retacrit Step J/Q Code: Q5106
Erbitux (PA)	Generic Name: cetuximab J/Q Code: J9055
Eylea (ST)	Generic Name: aflibercept J/Q Code: J9400 <hr/> Step Requirements: bevacizumab ophthalmic Step J/Q Code: J9035
Fabrazyme (PA)	Generic Name: agalsidase beta J/Q Code: J0180
Feraheme (ST)	Generic Name: ferumoxytol J/Q Code: Q0138/Q0139 <hr/> Step Requirements: Infed, Venofer Step J/Q Code: J1750, J1756

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Ferrlecit (ST)	<p>Generic Name: sodium ferric gluconate J/Q Code: J2916</p> <hr/> <p>Step Requirements: Infed, Venofer Step J/Q Code: J1750, J1756</p>
Epoprostenol (ST)	<p>Brand Name: Flolan Generic Name: epoprostenol J/Q Code: J1325 Step Requirements: ambrisentan, tadalafil, sildenafil Step J/Q Code:</p>
Fulphila (PA)	<p>Biosimilar for: Neulasta Generic Name: Peg-Filgrastim J/Q Code: Q5108</p>
Levoleucovorin (ST)	<p>Brand Name: Fusilev Generic Name: levoleucovorin J/Q Code: J0641 Step Requirements: leucovorin Step J/Q Code: J0640</p>
Gammagard (PA)	<p>Generic Name: Intravenous Immune Globulin J/Q Code: J1569</p>
Gamunex (PA)	<p>Generic Name: Intravenous Immune Globulin J/Q Code: J1561</p>

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Gazyva (ST)	<p>Generic Name: obinutuzumab J/Q Code: J9301</p> <hr/> <p>Step Requirements: Ruxience (preferred), Rituxan Step J/Q Code: J9312</p>
Geodon (ST)	<p>Generic Name: ziprasidone injection J/Q Code: J3486</p> <hr/> <p>Step Requirements: oral ziprasidone Step J/Q Code:</p>
Glassia (ST)	<p>Generic Name: alpha-1 proteinase inhibitor J/Q Code: J0257</p> <hr/> <p>Step Requirements: Prolastin Step J/Q Code: J0256</p>
Granix (ST)	<p>Biosimilar For: Neupogen Generic Name: filgrastim J/Q Code: j1447</p> <hr/> <p>Step Requirements: Zarzio, Nivestym Step J/Q Code:</p>
Herceptin, Herceptin Hylecta, Ontruzant,Herzuma, Orgivi (ST)	<p>Generic Name: trastuzumab J/Q Code: J9355, J9356</p> <hr/> <p>Step Requirements: Trazimera Kanjinti (preferred biosimilars) Step J/Q Code: Q5117 Q5112, Q5116,Q5114, Q5113</p>

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Hizentra (ST)	<p>Generic Name: Subcutaneous Immune Globulin J/Q Code: J1559</p> <hr/> <p>Step Requirements: Gammagard, Gammunex Step J/Q Code: J1569, J1561</p>
Hyquvia (ST)	<p>Generic Name: Subcutaneous Immune Globulin J/Q Code: J1575</p> <hr/> <p>Step Requirements: Gammagard, Gammunex Step J/Q Code: J1569, J1561</p>
Imfinzi (PA)	<p>Generic Name: durvalumab J/Q Code: J9173</p>
Imlygic (PA)	<p>Generic Name: talimogene laherparepvec J/Q Code: J9325</p>
Inflectra (ST)	<p>Biosimilar for: Remicade Generic Name: infliximab J/Q Code: Q5103</p> <hr/> <p>Step Requirements: Renflexis Step J/Q Code: Q5104</p>

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Injectafer (ST)	<p>Generic Name: ferric carboxymaltose J/Q Code: J1439</p> <hr/> <p>Step Requirements: Infed, Venofer Step J/Q Code: J1750, J1756</p>
Invega Sustenna (ST)	<p>Generic Name: paliperidone J/Q Code: J2426</p> <hr/> <p>Step Requirements: aripiprazole, paliperidone, risperidone Step J/Q Code:</p>
Ixempra (PA)	<p>Generic Name: ixabepilone J/Q Code: J9207</p>
Jevtana (PA)	<p>Generic Name: cabazitaxel J/Q Code: J9043</p>
Kadcyla (PA)	<p>Generic Name: ado-trastuzumab J/Q Code: J9354</p>
Keytruda (PA)	<p>Generic Name: pembrolizumab J/Q Code: J9271</p>
Krystexxa (ST)	<p>Generic Name: pegloticase J/Q Code: J2507</p> <hr/> <p>Step Requirements: allopurinol, febuxostat, Probenecid, colchicine, oral corticosteroids Step J/Q Code:</p>
Kyprolis (PA)	<p>Generic Name: carfilzomib J/Q Code: J9047</p>

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Levulan (PA)	Generic Name: aminolevulinic acid J/Q Code: J7308
Libtayo (PA)	Generic Name: cemiplimab J/Q Code: J9119
Lucentis (ST)	Generic Name: Ranibizumab J/Q Code: J2778 Step Requirements: bevacizumab ophthalmic Step J/Q Code: J9035
myobloc (PA)	Generic Name: rimabotulinum J/Q Code: j0587
Neulasta, Nyvepria, Ziextenzo (ST)	Generic Name: Peg- Filgrastim J/Q Code: J2505 Step Requirements: Fulphila , Udenyca, Step J/Q Code: Q5108, Q5111,Q5120, Q5122
Neupogen (ST)	Generic Name: filgrastim J/Q Code: j1442 Step Requirements: Granix, Zarxio, Nivestym (preferred) Step J/Q Code: J1447, Q5101, Q5110
Nplate (PA)	Generic Name: romiplostim J/Q Code: J2796

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Nulojix (ST)	Generic Name: belatacept J/Q Code: J0485 <hr/> Step Requirements: cyclosporine, tacrolimus Step J/Q Code:
Ocrevus (ST)	Generic Name: ocrelizumab J/Q Code: J2350 <hr/> Step Requirements: Glatopa (preferred), Gilenya Step J/Q Code:
Octagam (PA)	Generic Name: Intravenous Immune Globulin J/Q Code: J1568
Opdivo (PA)	Generic Name: nivolumab J/Q Code: J9299
Orencia (ST)	Generic Name: abatacept J/Q Code: J0129 <hr/> Step Requirements: Renflexis, Kevzara, Xeljanz, Simponi, Enbrel Step J/Q Code: Q5104
Parsabiv (ST)	Generic Name: etelcalcetide J/Q Code: <hr/> Step Requirements: calcitriol, cinacalcet, paracalcitol Step J/Q Code: J0604, J2501

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Perjeta (PA)	Generic Name: pertuzumab J/Q Code: J9306
Privigen (PA)	Generic Name: Intravenous Immune Globulin J/Q Code: J1459
Procrit (ST)	Generic Name: epoetin alpha J/Q Code: j0885 Q4081 Step Requirements: Retacrit Step J/Q Code: Q5106
Prolastin, Aralast, Zemaira (PA)	Generic Name: alpha-1 proteinase inhibitor J/Q Code: J0256
Prolia (ST)	Generic Name: denosumab J/Q Code: J0897 Step Requirements: zoledronic acid Step J/Q Code: J3489
Provenge (PA)	Generic Name: sipuleucel-T J/Q Code: Q2043
Pulmozyme (PA)	Generic Name: dornase alfa J/Q Code: J7639
Radicava (PA)	Generic Name: edaravone J/Q Code: J1301
Remicade (ST)	Generic Name: infliximab J/Q Code: J1745 Step Requirements: Renflexis Step J/Q Code: Q5104

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Remodulin (ST)	<p>Generic Name: treprostinil</p> <p>J/Q Code: J3285</p> <hr/> <p>Step Requirements: ambrisentan, tadalafil, sildenafil</p> <p>Step J/Q Code:</p>
Renflexis (ST)	<p>Biosimilar for: Remicade</p> <p>Generic Name: infliximab</p> <p>J/Q Code: Q5104</p> <hr/> <p>Step Requirements: RA: methotrexate, leflunomide, hydroxychloroquine, sulfasalazine PP: MTX, acitretin, topical corticosteroids, topical vitamin D analog PsA: MTX, LEF Crohn's/UC: azathioprine, 6-MP, MTX, 5-asa, sulfasalazine, balsalazide, mesalamine</p> <p>Step J/Q Code:</p>
Rituxan, Rituxan Hycela, Truxima (ST)	<p>Generic Name: rituximab</p> <p>J/Q Code: J9312,Q5115,J9311</p> <hr/> <p>Step Requirements: Ruxience</p> <p>Step J/Q Code:</p>

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Rituxan Hycela (ST)	<p>Generic Name: rituximab hyaluronidase J/Q Code: J9311</p> <hr/> <p>Step Requirements: Ruxience (preferred), Rituxan Step J/Q Code: J9312</p>
Ruxience (PA)	<p>Brand Name: Ruxience Generic Name: rituximab J/Q Code:</p>
Sancuso (ST)	<p>Generic Name: granisetron J/Q Code:</p> <hr/> <p>Step Requirements: generic ondansetron (IV/oral), generic granisetron (oral/IV), aprepitant, fosaprepitant, Aloxi, and low-dose olanzapine (when supported by NCCN guidelines) Step J/Q Code: J1626, J2405, J2469</p>
Sandostatin LAR (ST)	<p>Generic Name: octreotide depot J/Q Code: J2353</p> <hr/> <p>Step Requirements: octreotide non-depot Step J/Q Code: J2354</p>

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Simponi ARIA (ST)	<p>Generic Name: golimumab J/Q Code: J1602</p> <hr/> <p>Step Requirements: Renflexis, Kevzara Step J/Q Code: Q5104</p>
Sinuva (ST)	<p>Generic Name: Mometasone J7402</p> <hr/> <p>Step Requirements Fluticasone, Budesonide neb J7626</p>
Soliris (ST)	<p>Generic Name: eculizumab J/Q Code: J1300</p> <hr/> <p>Step Requirements: MG: pyridostigmine, corticosteroids, azathioprine, cyclosporine, mycophenolate, tacrolimus, methotrexate, cyclophosphamide, IVIg, SCIG, rituximab, Satralizumab (For NMSOD) Step J/Q Code: J9312, J1569, J1561, J1559, J1555, J1575</p>

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<p>Somatuline depot (ST)</p>	<p>Generic Name: lanreotide J/Q Code: J1930</p> <hr/> <p>Step Requirements: octreotide non depot, octreotide depot Step J/Q Code: J2354, J2353</p>
<p>Stelara (ST)</p>	<p>Generic Name: ustekinumab J/Q Code: J3357</p> <hr/> <p>Step Requirements: PP: Renflexis, Enbrel PsA: Renflexis, Enbrel, Xeljanz, Simponi Crohn's: Renflexis (preferred over Entyvio and Humira), Entyvio (preferred over Humira), Humira UC: Renflexis (preferred over Entyvio and Humira), Entyvio (preferred over Humira), Humira, Xeljanz, Simponi Step J/Q Code: Q5104, J1602, J3380</p>

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Sustol (ST)	<p>Generic Name: granisetron J/Q Code: J1627</p> <hr/> <p>Step Requirements: generic ondansetron (IV/oral), generic granisetron (oral/IV), aprepitant, fosaprepitant, Aloxi, and low-dose olanzapine (when supported by NCCN guidelines) Step J/Q Code: J1626, J2405, J2469</p>
Sylvant (PA)	<p>Generic Name: siltuximab J/Q Code: J2860</p>
Tecentriq (PA)	<p>Generic Name: atezolizumab J/Q Code: J9022</p>
Treanda (PA)	<p>Generic Name: bendamustine J/Q Code: J9033</p>
Trisenox (PA)	<p>Generic Name: arsenic trioxide J/Q Code: J9017</p>

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Tysabri (ST)	<p>Generic Name: natalizumab J/Q Code: J2323</p> <hr/> <p>Step Requirements: MS: Glatopa, Gilenya (preferred), Ocrevus, Tecfidera Crohn's: Renflexis (preferred over Entyvio and Humira), Entyvio (preferred over Humira), Humira Step J/Q Code: J2350, J3380</p>
Udenyca (PA)	<p>Biosimilar for: Neulasta Generic Name: Peg-Filgrastim J/Q Code: Q5111</p>
Varubi (ST)	<p>Generic Name: rolapitant J/Q Code: J8670</p> <hr/> <p>Step Requirements: generic ondansetron (IV/oral), generic granisetron (oral/IV), aprepitant, fosaprepitant, Aloxi, and low-dose olanzapine (when supported by NCCN guidelines) Step J/Q Code: J1626, J2405, J2469</p>
Vectibix (PA)	<p>Generic Name: panitumumab J/Q Code: J9303</p>
Velcade (PA)	<p>Generic Name: bortezomib J/Q Code: J9044</p>

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Ventavis (PA)	Generic Name: iloprost J/Q Code: Q4074
Xeomin (PA)	Generic Name: incobotulinum J/Q Code: J0588
Xgeva (ST)	Generic Name: denosumab J/Q Code: J0897 Step Requirements: zoledronic acid Step J/Q Code: J3488
Xiaflex (PA)	Generic Name: collagenase J/Q Code: J0775
Ziextenzo	Generic Name: Peg-Filgrastim bmez J/Q Code: Q5120 Step Requirements: Fulphila , Udenyca, Step J/Q Code: Q5108, Q5111
Xolair (PA)	Generic Name: omalizumab J/Q Code: J2357
Yervoy (PA)	Generic Name: ipilimumab J/Q Code: J9228
Zaltrap (ST)	Generic Name: ziv-aflibercept J/Q Code: J9400 Step Requirements: Zirabev, MVASI (preferred), Avastin Step J/Q Code: Q5118, Q5107, J9035
Zarxio (PA)	Biosimilar for: Neupogen Generic Name: filgrastim J/Q Code: Q5101

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Zilretta (ST)	<p>Generic Name: Triamcinolone extended release J/Q Code: J3304</p> <hr/> <p>Step Requirements: Triamcinolone, Methylprednisolone Step J/Q Code: J3301, J2930</p>

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