Updated: 01/2020 PARP Approved: 02/2020

## Prior Authorization Criteria <u>Oxbryta (voxelotor)</u>

All requests for Oxbryta (voxelotor) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Coverage may be provided with a <u>diagnosis</u> of the treatment of Sickle Cell Disease and the following criteria is met:

- Member is 12 years of age or older.
- Diagnosis is confirmed by electrophoresis demonstrating the presence of sickle cell disease (HbSS, HbSC, HbSβ<sup>o</sup>-thalassemia, or HbSβ<sup>+</sup>-thalassemia).
- Member must have a hemoglobin ≥5.5 g/dL.
- Must be prescribed by or in association with hematologist/oncologist or sickle cell disease specialist.
- Must provide documentation showing the member has tried and failed (which will be verified via pharmacy claims if available) or had an intolerance or contraindication to at least a 6 month trial of hydroxyurea.
- Member must have had at least 1 vaso-occlusive crisis in the past 12 months.
- Member must not have severe renal dysfunction (estimated glomerular filtration rate at the Screening visit; calculated by the central laboratory) <30 mL/min/1.73 m<sup>2</sup> or on chronic dialysis.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.
- Initial Duration of Approval: 6 months
  - There must be clinical documentation that there has been a reduction in vasoocclusive events, and/or increased hemoglobin response rate defined as a Hb increase of more than 1 g/dL.
- Reauthorization Duration of Approval: 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.



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## OXBRYTA (VOXELOTOR) PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health<sup>SM</sup> Pharmacy Services. **FAX:** (888) 245-2049

If needed, you may call to speak to a Pharmacy Services Representative.

| PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm  |          |           |  |  |  |  |
|---|----------|-----------|--|--|--|--|
| PROVIDER IN   | FORMA    | TION      |  |  |  |  |
| Requesting Provider:  |          | NF        | ના:  |  |  |  |
| Provider Specialty:   |          | Of        | fice Contact:                                |  |  |  |
| Office Address:   |          | Of        | fice Phone:                                  |  |  |  |
|   |          | Of        | fice Fax:                                    |  |  |  |
| MEMBER INFORMATION  |          |           |  |  |  |  |
| Member Name: DOB:   |          |           |  |  |  |  |
| Gateway ID: Member v  |          |           | eight:kg                                     |  |  |  |
| REQUESTED DRUG INFORMATION  |          |           |  |  |  |  |
| Medication:   | Strer    | gth:      |  |  |  |  |
| Frequency:  | Dura     | Duration: |  |  |  |  |
| Is the member currently receiving requested medication?  Y  | es 🗌     | No        | Date Medication Initiated:                   |  |  |  |
| Billing Information   |          |           |  |  |  |  |
| This medication will be billed: at a pharmacy <b>OR</b>   |          |           |  |  |  |  |
| medically (if medically please p  | rovide   | a JCO     | DE:  |  |  |  |
| Place of Service: Hospital Provider's office Memb   | er's ho  | me [      | Other  |  |  |  |
| Place of Servic   | e Inforr | natio     | n  |  |  |  |
| Name:   |          | NF        | 기:   |  |  |  |
| Address:  |          | Phone:    |  |  |  |  |
|   |          |           |  |  |  |  |
| MEDICAL HISTORY (Com  | plete f  | or AL     | L requests)                                  |  |  |  |
| 1. Is member 12 years of age or older?  |          |           |  |  |  |  |
| ☐ Yes ☐ No  |          |           |  |  |  |  |
|   |          |           |  |  |  |  |
| 2. Has the diagnosis is confirmed by electrophoresis demonstrating the presence of sickle cell disease (HbSS, HbSC,   |          |           |  |  |  |  |
| HbS $\beta$ <sup>o</sup> -thalassemia, or HbS $\beta$ <sup>+</sup> -thalassemia)?   |          |           |  |  |  |  |
| ☐ Yes ☐ No  |          |           |  |  |  |  |
|   |          |           |  |  |  |  |
| 3. Does the member have a hemoglobin ≥5.5 g/dL?   |          |           |  |  |  |  |
| ∐ Yes □ No  |          |           |  |  |  |  |
| 4 Milliaha gaadisatian ka gusagihad ku ay is asasistian   | ما ماهان |           |  |  |  |  |
| 4. Will the medication be prescribed by or in association with hematologist/oncologist or sickle cell disease specialist?  ☐ Yes ☐ No   |          |           |  |  |  |  |
| res No  |          |           |  |  |  |  |
| 5. Is the documentation showing the member has tried a  | nd faile | d (wh     | nich will be verified via pharmacy claims if |  |  |  |
| 5. Is the documentation showing the member has tried and failed (which will be verified via pharmacy claims if available) or had an intolerance or contraindication to at least a 6 month trial of hydroxyurea? If yes, please attach |          |           |  |  |  |  |
| documentation.  |          |           |  |  |  |  |
| Yes No  |          |           |  |  |  |  |
|   |          |           |  |  |  |  |



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| 6. Has the member had a  | t least 1 vaso-occlusive crisis i                              | in the past 12 months? | ?   |  |  |
|--|--|------------------------|---|--|--|
|  | e severe renal dysfunction (es<br>al laboratory) <30 mL/min/1. | •                      | tration rate at the Screening visit;<br>dialysis? |  |  |
|  | CURRENT or P   | REVIOUS THERAPY        |   |  |  |
| Medication Name  | edication Name Strength/ Frequency Dates of Therap             | Dates of Therapy       | Status (Discontinued & Why/Current)               |  |  |
|  |  |                        |   |  |  |
|  |  |                        |   |  |  |
|  |  | IORIZATION             |   |  |  |
| Is there clinical documentation response rate defined as a Hb Yes No  Please describe: | that there has been a reducti                                  | on in vaso-occlusive e | vents and/or increased hemoglobin                 |  |  |
|  | SUPPORTING INFORMAT  | TION or CLINICAL RATI  | ONALE   |  |  |
|  |  |                        |   |  |  |
|  |  |                        |   |  |  |
| Prescribing Prov   | vider Signature  |                        | Date  |  |  |
|  |  |                        |   |  |  |