

## Texas Prior Authorization Program Clinical Criteria

---

### Drug/Drug Class

## Sickle Cell Disease Agents

*This criteria was recommended for review by the Vendor Drug Program to ensure appropriate and safe utilization*

### Clinical Information Included in this Document

#### Oxbryta (Voxelotor)

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram:** a visual depiction of the clinical criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes)
- **References:** clinical publications and sources relevant to this clinical criteria

**Note:** Click the hyperlink to navigate directly to that section.

### Revision Notes

Added GCN for Oxbryta (53456) to PA drug table



## Oxbryta (Voxeletor)

### Drugs Requiring Prior Authorization

The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit [TxVendorDrug.com/formulary/formulary-search](https://TxVendorDrug.com/formulary/formulary-search).

| Drugs Requiring Prior Authorization       |       |
|---|-------|
| Label Name                                | GCN   |
| OXBRYTA 500 MG TABLET                     | 47372 |
| OXBRYTA 300 MG TABLET                     | 53456 |
| OXBRYTA 300 MG TABLET FOR ORAL SUSPENSION | 51717 |



## Oxbryta (Voxeletor)

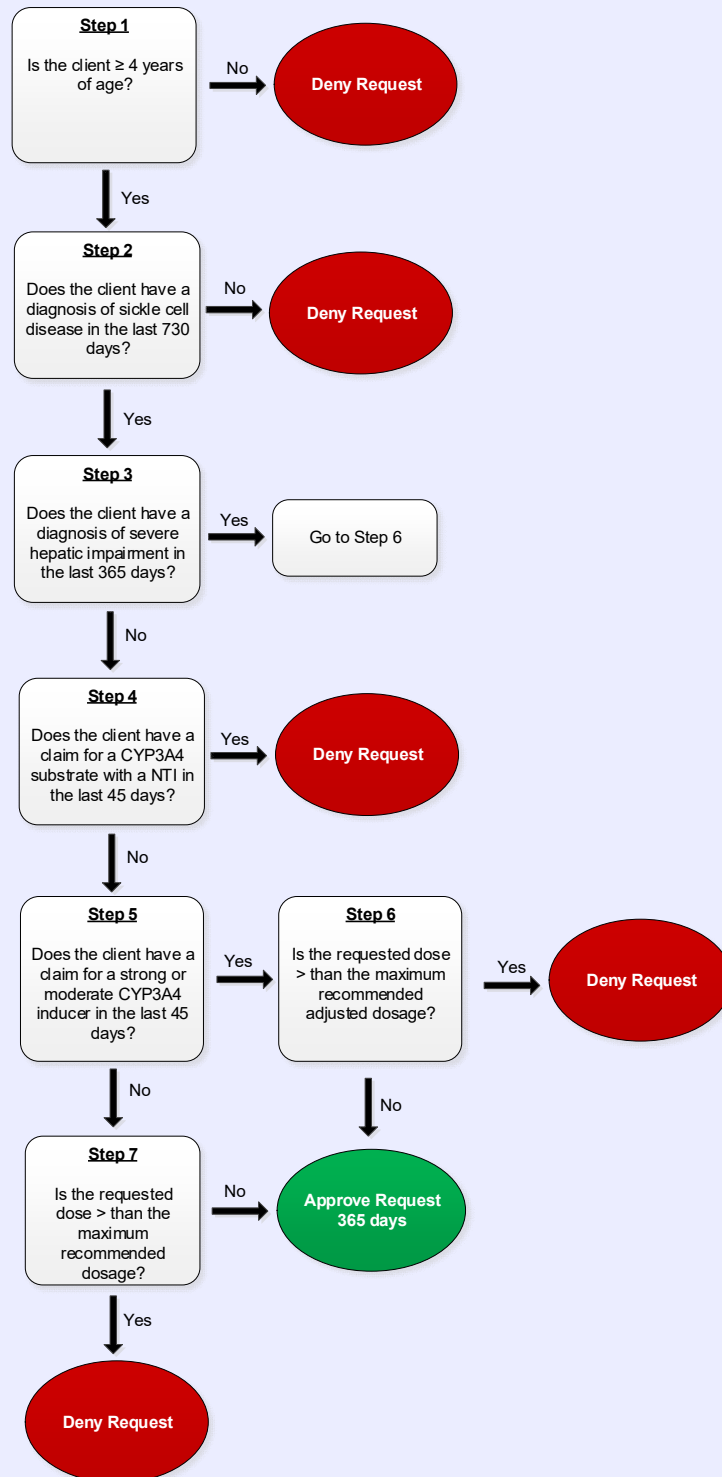
### Clinical Criteria Logic

1. Is the client greater than or equal to ( $\geq$ ) 4 years of age?  
 Yes (Go to #2)  
 No (Deny)
2. Does the client have a diagnosis of **sickle cell disease** in the last 730 days?  
 Yes (Go to #3)  
 No (Deny)
3. Does the client have a diagnosis of **severe hepatic impairment** in the last 365 days?  
 Yes (Go to #6)  
 No (Go to #4)
4. Does the client have a claim for a **CYP3A4 substrate with a narrow therapeutic index (NTI)** in the last 45 days?  
 Yes (Deny)  
 No (Go to #5)
5. Does the client have a claim for a **strong or moderate CYP3A4 inducer** in the last 45 days?  
 Yes (Go to #6)  
 No (Go to #7)
6. Is the requested dose greater than ( $>$ ) the maximum recommended adjusted dosage (**Table 6**)?  
 Yes (Deny)  
 No (Approve – 365 days)
7. Is the requested dose greater than ( $>$ ) the maximum recommended dosage (**Table 7**)?  
 Yes (Deny)  
 No (Approve – 365 days)



# Oxbryta (Voxeletor)

## Clinical Criteria Logic Diagram





## Oxbryta (Voxeletor)

### Clinical Criteria Supporting Tables

| <b>Step 2 (diagnosis of sickle cell disease)</b> |  |
|--|--|
| <b>Required diagnosis: 1</b>                     |  |
| <b>Look back timeframe: 730 days</b>             |  |
| <b>ICD-10 Code</b>                               | <b>Description</b>                                     |
| D5700  | HB-SS DISEASE WITH CRISIS UNSPECIFIED                  |
| D5701  | HB-SS DISEASE WITH ACUTE CHEST SYNDROME                |
| D5702  | HB-SS DISEASE WITH SPLENIC SEQUESTRATION               |
| D571   | SICKLE-CELL DISEASE WITHOUT CRISIS                     |
| D5720  | SICKLE-CELL/HB-C DISEASE WITHOUT CRISIS                |
| D57211   | SICKLE-CELL/HB-C DISEASE WITH ACUTE CHEST SYNDROME     |
| D57212   | SICKLE-CELL/HB-C DISEASE WITH SPLENIC SEQUESTRATION    |
| D57219   | SICKLE-CELL/HB-C DISEASE WITH CRISIS UNSPECIFIED       |
| D5740  | SICKLE-CELL THALASSEMIA WITHOUT CRISIS                 |
| D57411   | SICKLE-CELL THALASSEMIA WITH ACUTE CHEST SYNDROME      |
| D57412   | SICKLE-CELL THALASSEMIA WITH SPLENIC SEQUESTRATION     |
| D57419   | SICKLE-CELL THALASSEMIA WITH CRISIS UNSPECIFIED        |
| D5780  | OTHER SICKLE-CELL DISORDERS WITHOUT CRISIS             |
| D57811   | OTHER SICKLE-CELL DISORDERS WITH ACUTE CHEST SYNDROME  |
| D57812   | OTHER SICKLE-CELL DISORDERS WITH SPLENIC SEQUESTRATION |
| D57819   | OTHER SICKLE-CELL DISORDERS WITH CRISIS UNSPECIFIED    |

| <b>Step 3 (diagnosis of severe hepatic impairment)</b> |  |
|--|--|
| <b>Required diagnosis: 1</b>                           |  |
| <b>Look back timeframe: 365 days</b>                   |  |
| <b>ICD-10 Code</b>                                     | <b>Description</b>                                 |
| B180   | CHRONIC VIRAL HEPATITIS B WITH DELTA-AGENT         |
| B181   | CHRONIC VIRAL HEPATITIS B WITHOUT DELTA-AGENT      |
| B182   | CHRONIC VIRAL HEPATITIS C                          |
| B188   | OTHER CHRONIC VIRAL HEPATITIS                      |
| B189   | CHRONIC VIRAL HEPATITIS, UNSPECIFIED               |
| B190   | UNSPECIFIED VIRAL HEPATITIS WITH HEPATIC COMA      |
| B1910  | UNSPECIFIED VIRAL HEPATITIS B WITHOUT HEPATIC COMA |
| B1911  | UNSPECIFIED VIRAL HEPATITIS B WITH HEPATIC COMA    |
| B1920  | UNSPECIFIED VIRAL HEPATITIS C WITHOUT HEPATIC COMA |

| <b>Step 3 (diagnosis of severe hepatic impairment)</b> |   |
|--|---|
| <b>Required diagnosis: 1</b>                           |   |
| <b>Look back timeframe: 365 days</b>                   |   |
| <b>ICD-10 Code</b>                                     | <b>Description</b>  |
| B1921  | UNSPECIFIED VIRAL HEPATITIS C WITH HEPATIC COMA                   |
| B199   | UNSPECIFIED VIRAL HEPATITIS WITHOUT HEPATIC COMA                  |
| K700   | ALCOHOLIC FATTY LIVER   |
| K7010  | ALCOHOLIC HEPATITIS WITHOUT ASCITES                               |
| K7011  | ALCOHOLIC HEPATITIS WITH ASCITES                                  |
| K702   | ALCOHOLIC FIBROSIS AND SCLEROSIS OF LIVER                         |
| K7030  | ALCOHOLIC CIRRHOSIS OF LIVER WITHOUT ASCITES                      |
| K7031  | ALCOHOLIC CIRRHOSIS OF LIVER WITH ASCITES                         |
| K7040  | ALCOHOLIC HEPATIC FAILURE WITHOUT COMA                            |
| K7041  | ALCOHOLIC HEPATIC FAILURE WITH COMA                               |
| K709   | ALCOHOLIC LIVER DISEASE, UNSPECIFIED                              |
| K710   | TOXIC LIVER DISEASE WITH CHOLESTASIS                              |
| K7110  | TOXIC LIVER DISEASE WITH HEPATIC NECROSIS WITHOUT COMA            |
| K7111  | TOXIC LIVER DISEASE WITH HEPATIC NECROSIS WITH COMA               |
| K712   | TOXIC LIVER DISEASE WITH ACUTE HEPATITIS                          |
| K713   | TOXIC LIVER DISEASE WITH CHRONIC PERSISTENT HEPATITIS             |
| K714   | TOXIC LIVER DISEASE WITH CHRONIC LOBULAR HEPATITIS                |
| K7150  | TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITHOUT ASCITES |
| K7151  | TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITH ASCITES    |
| K716   | TOXIC LIVER DISEASE WITH HEPATITIS, NOT ELSEWHERE CLASSIFIED      |
| K717   | TOXIC LIVER DISEASE WITH FIBROSIS AND CIRRHOSIS OF LIVER          |
| K718   | TOXIC LIVER DISEASE WITH OTHER DISORDERS OF LIVER                 |
| K719   | TOXIC LIVER DISEASE, UNSPECIFIED                                  |
| K7200  | ACUTE AND SUBACUTE HEPATIC FAILURE WITHOUT COMA                   |
| K7201  | ACUTE AND SUBACUTE HEPATIC FAILURE WITH COMA                      |
| K7210  | CHRONIC HEPATIC FAILURE WITHOUT COMA                              |
| K7211  | CHRONIC HEPATIC FAILURE WITH COMA                                 |
| K7290  | HEPATIC FAILURE, UNSPECIFIED WITHOUT COMA                         |
| K7291  | HEPATIC FAILURE, UNSPECIFIED WITH COMA                            |
| K730   | CHRONIC PERSISTENT HEPATITIS, NOT ELSEWHERE CLASSIFIED            |
| K731   | CHRONIC LOBULAR HEPATITIS, NOT ELSEWHERE CLASSIFIED               |
| K732   | CHRONIC ACTIVE HEPATITIS, NOT ELSEWHERE CLASSIFIED                |
| K738   | OTHER CHRONIC HEPATITIS, NOT ELSEWHERE CLASSIFIED                 |
| K739   | CHRONIC HEPATITIS, UNSPECIFIED                                    |
| K740   | HEPATIC FIBROSIS  |

| <b>Step 3 (diagnosis of severe hepatic impairment)</b> |   |
|--|---|
| <b>Required diagnosis: 1</b>                           |   |
| <b>Look back timeframe: 365 days</b>                   |   |
| <b>ICD-10 Code</b>                                     | <b>Description</b>                          |
| K741   | HEPATIC SCLEROSIS                           |
| K742   | HEPATIC FIBROSIS WITH HEPATIC SCLEROSIS     |
| K743   | PRIMARY BILIARY CIRRHOSIS                   |
| K744   | SECONDARY BILIARY CIRRHOSIS                 |
| K745   | BILIARY CIRRHOSIS, UNSPECIFIED              |
| K7460  | UNSPECIFIED CIRRHOSIS OF LIVER              |
| K7469  | OTHER CIRRHOSIS OF LIVER                    |
| K7589  | OTHER SPECIFIED INFLAMMATORY LIVER DISEASES |

| <b>Step 4 (history of a CYP3A4 substrate with a NTI)</b> |            |
|--|------------|
| <b>Number of claims: 1</b>                               |            |
| <b>Look back timeframe: 45 days</b>                      |            |
| <b>Label Name</b>  | <b>GCN</b> |
| AFINITOR 10 MG TABLET                                    | 20844      |
| AFINITOR 2.5 MG TABLET                                   | 28783      |
| AFINITOR 5 MG TABLET                                     | 20784      |
| AFINITOR 7.5 MG TABLET                                   | 31396      |
| AFINITOR DISPERZ 2 MG TABLET                             | 34589      |
| AFINITOR DISPERZ 3 MG TABLET                             | 34590      |
| AFINITOR DISPERZ 5 MG TABLET                             | 34592      |
| ASTAGRAF XL 0.5 MG CAPSULE                               | 98662      |
| ASTAGRAF XL 1 MG CAPSULE                                 | 98663      |
| ASTAGRAF XL 5 MG CAPSULE                                 | 98664      |
| ENVARUSUS XR 0.75 MG TABLET                              | 39120      |
| ENVARUSUS XR 1 MG TABLET                                 | 39123      |
| ENVARUSUS XR 4 MG TABLET                                 | 39124      |
| PROGRAF 0.2 MG GRANULE PACKET                            | 28251      |
| PROGRAF 0.5 MG CAPSULE                                   | 28495      |
| PROGRAF 1 MG CAPSULE                                     | 28491      |
| PROGRAF 1 MG GRANULE PACKET                              | 28249      |
| PROGRAF 5 MG CAPSULE                                     | 28492      |
| RAPAMUNE 0.5 MG TABLET                                   | 28502      |
| RAPAMUNE 1 MG TABLET                                     | 13696      |
| RAPAMUNE 1 MG/ML ORAL SOLN                               | 50356      |
| RAPAMUNE 2 MG TABLET                                     | 19299      |
| SIROLIMUS 0.5 MG TABLET                                  | 28502      |

| <b>Step 4 (history of a CYP3A4 substrate with a NTI)</b> |            |
|--|------------|
| <b>Number of claims: 1</b>                               |            |
| <b>Look back timeframe: 45 days</b>                      |            |
| <b>Label Name</b>  | <b>GCN</b> |
| SIROLIMUS 1 MG TABLET                                    | 13696      |
| SIROLIMUS 1 MG/ML SOLUTION                               | 50356      |
| SIROLIMUS 2 MG TABLET                                    | 19299      |
| TACROLIMUS 0.5 MG CAPSULE                                | 28495      |
| TACROLIMUS 1 MG CAPSULE                                  | 28491      |
| TACROLIMUS 5 MG CAPSULE                                  | 28492      |
| ZORTRESS 0.25 MG TABLET                                  | 24825      |
| ZORTRESS 0.5 MG TABLET                                   | 24826      |
| ZORTRESS 0.75 MG TABLET                                  | 24827      |
| ZORTRESS 1 MG TABLET                                     | 28589      |

| <b>Step 5 (history of a strong or moderate CYP3A4 inducer)</b> |            |
|--|------------|
| <b>Number of claims: 1</b>                                     |            |
| <b>Look back timeframe: 45 days</b>                            |            |
| <b>Label Name</b>  | <b>GCN</b> |
| APTIOM 200 MG TABLET   | 36098      |
| APTIOM 400 MG TABLET   | 36099      |
| APTIOM 600 MG TABLET   | 36106      |
| APTIOM 800 MG TABLET   | 27409      |
| ASACOMP WITH CODEINE CAPSULE                                   | 69500      |
| ATRIPLA TABLET   | 27346      |
| BEXAROTENE 75 MG CAPSULE                                       | 92373      |
| BOSENTAN 125 MG TABLET   | 14978      |
| BOSENTAN 62.5MG TABLET   | 14979      |
| BUPAP 50 MG-300 MG TABLET                                      | 31623      |
| BUTALB-ACETAMIN-CAFF 50-300-40                                 | 28626      |
| BUTALBITAL-ACETAMINOPHN 50-325                                 | 72711      |
| BUTALB-ACETAMIN-CAFF 50-325-40                                 | 72510      |
| BUTALB-ACETAMIN-CAFF 50-325-40                                 | 72530      |
| BUTALB-ACETAMINOPH-CAFF-CODEIN                                 | 34988      |
| BUTALB-ASPIRIN-CAFFE 50-325-40                                 | 71160      |
| BUTALB-CAFF-ACETAMINOPH-CODEIN                                 | 70140      |
| BUTALBITAL COMP-CODEINE #3 CAP                                 | 69500      |
| BUTALBITAL-ACETAMINOPHN 50-300                                 | 31623      |
| BUTALBITAL-ACETAMINOPHN 50-300                                 | 45029      |
| BUTALBITAL-ASA-CAFFEINE CAP                                    | 71150      |
| CARBAMAZEPINE 100 MG TAB CHEW                                  | 17460      |



| <b>Step 5 (history of a strong or moderate CYP3A4 inducer)</b> |            |
|--|------------|
| <b>Number of claims: 1</b>                                     |            |
| <b>Look back timeframe: 45 days</b>                            |            |
| <b>Label Name</b>  | <b>GCN</b> |
| CARBAMAZEPINE 100 MG/5 ML SUSP                                 | 47500      |
| CARBAMAZEPINE 200 MG TABLET                                    | 17450      |
| CARBAMAZEPINE ER 100 MG CAP                                    | 23934      |
| CARBAMAZEPINE ER 100 MG TAB                                    | 27820      |
| CARBAMAZEPINE ER 200 MG CAP                                    | 23932      |
| CARBAMAZEPINE ER 200 MG TABLET                                 | 27821      |
| CARBAMAZEPINE ER 300 MG CAP                                    | 23933      |
| CARBAMAZEPINE ER 400 MG TABLET                                 | 27822      |
| CARBATROL ER 100 MG CAPSULE                                    | 23934      |
| CARBATROL ER 200 MG CAPSULE                                    | 23932      |
| CARBATROL ER 300 MG CAPSULE                                    | 23933      |
| DEXAMETHASONE 0.5 MG TABLET                                    | 27422      |
| DEXAMETHASONE 0.5 MG/5 ML ELX                                  | 27400      |
| DEXAMETHASONE 0.5 MG/5 ML LIQ                                  | 27411      |
| DEXAMETHASONE 0.75 MG TABLET                                   | 27425      |
| DEXAMETHASONE 1 MG TABLET                                      | 27424      |
| DEXAMETHASONE 1.5 MG TABLET                                    | 27427      |
| DEXAMETHASONE 2 MG TABLET                                      | 27426      |
| DEXAMETHASONE 4 MG TABLET                                      | 27428      |
| DEXAMETHASONE 4 MG/ML VIAL                                     | 27354      |
| DEXAMETHASONE 6 MG TABLET                                      | 27429      |
| DEXAMETHASONE INTENSOL 1 MG/ML                                 | 27412      |
| DILANTIN 100 MG CAPSULE  | 17700      |
| DILANTIN 125 MG/5 ML SUSP                                      | 17241      |
| DILANTIN 30 MG CAPSULE   | 17701      |
| DILANTIN 50 MG INFATAB   | 17250      |
| EFAVIRENZ 50 MG CAPSULE  | 43301      |
| EFAVIRENZ 600 MG TABLET  | 15555      |
| EPITOL 200 MG TABLET   | 17450      |
| EQUETRO 100 MG CAPSULE   | 13781      |
| EQUETRO 200 MG CAPSULE   | 13805      |
| EQUETRO 300 MG CAPSULE   | 13818      |
| ESGIC 50-325-40 MG TABLET                                      | 72530      |
| ESGIC CAPSULE  | 72510      |
| FIORICET 50-300-40 MG CAPSULE                                  | 28626      |
| FIORINAL WITH CODEINE #3                                       | 69500      |
| INTELENCE 100 MG TABLET  | 99318      |
| INTELENCE 200 MG TABLET  | 29424      |

| <b>Step 5 (history of a strong or moderate CYP3A4 inducer)</b> |            |
|--|------------|
| <b>Number of claims: 1</b>                                     |            |
| <b>Look back timeframe: 45 days</b>                            |            |
| <b>Label Name</b>  | <b>GCN</b> |
| INTELENCE 25 MG TABLET   | 32035      |
| LYSODREN 500 MG TABLET   | 37810      |
| MODAFINIL 100 MG TABLET  | 26101      |
| MODAFINIL 200 MG TABLET  | 26102      |
| MYCOBUTIN 150 MG CAPSULE                                       | 29810      |
| MYSOLINE 250 MG TABLET   | 17321      |
| MYSOLINE 50 MG TABLET  | 17322      |
| ORILISSA 150 MG TABLET   | 45026      |
| ORILISSA 200 MG TABLET   | 45028      |
| ORKAMBI 100-125 MG GRANULE PKT                                 | 36937      |
| ORKAMBI 100-125 MG TABLET                                      | 42366      |
| ORKAMBI 150-188 MG GRANULE PKT                                 | 42848      |
| ORKAMBI 200-125 MG TABLET                                      | 39008      |
| PHENOBARBITAL 130 MG/ML VIAL                                   | 12892      |
| PHENOBARBITAL 15 MG TABLET                                     | 12971      |
| PHENOBARBITAL 16.2 MG TABLET                                   | 97706      |
| PHENOBARBITAL 20 MG/5 ML ELIX                                  | 12956      |
| PHENOBARBITAL 30 MG TABLET                                     | 12973      |
| PHENOBARBITAL 32.4 MG TABLET                                   | 97965      |
| PHENOBARBITAL 60 MG TABLET                                     | 12972      |
| PHENOBARBITAL 64.8 MG TABLET                                   | 97966      |
| PHENOBARBITAL 65 MG/ML VIAL                                    | 12894      |
| PHENOBARBITAL 97.2 MG TABLET                                   | 97967      |
| PHENYTEK 200 MG CAPSULE  | 15038      |
| PHENYTEK 300 MG CAPSULE  | 15037      |
| PHENYTOIN 125 MG/5 ML SUSP                                     | 17241      |
| PHENYTOIN 50 MG TABLET CHEW                                    | 17250      |
| PHENYTOIN 50 MG/ML VIAL  | 17200      |
| PHENYTOIN SOD EXT 100 MG CAP                                   | 17700      |
| PHENYTOIN SOD EXT 200 MG CAP                                   | 15038      |
| PHENYTOIN SOD EXT 300 MG CAP                                   | 15037      |
| PRIFTIN 150 MG TABLET  | 45911      |
| PRIMIDONE 250 MG TABLET  | 17321      |
| PRIMIDONE 50 MG TABLET   | 17322      |
| PROVIGIL 100 MG TABLET   | 26101      |
| PROVIGIL 200 MG TABLET   | 26102      |
| RIFABUTIN 150 MG CAPSULE                                       | 29810      |
| RIFADIN 150 MG CAPSULE   | 41260      |

| <b>Step 5 (history of a strong or moderate CYP3A4 inducer)</b> |            |
|--|------------|
| <b>Number of claims: 1</b>                                     |            |
| <b>Look back timeframe: 45 days</b>                            |            |
| <b>Label Name</b>  | <b>GCN</b> |
| RIFADIN 300 MG CAPSULE   | 41261      |
| RIFADIN IV 600 MG VIAL   | 41470      |
| RIFAMATE CAPSULE   | 89800      |
| RIFAMPIN 150 MG CAPSULE  | 41260      |
| RIFAMPIN 300 MG CAPSULE  | 41261      |
| RIFAMPIN IV 600 MG VIAL  | 41470      |
| RIFATER TABLET   | 14142      |
| SUSTIVA 200 MG CAPSULE   | 43303      |
| SUSTIVA 50 MG CAPSULE  | 43301      |
| SUSTIVA 600 MG TABLET  | 15555      |
| SYMFI 600-300-300 MG TABLET                                    | 44548      |
| SYMFI LO 400-300-300 MG TABLET                                 | 44425      |
| TAFINLAR 50 MG CAPSULE   | 34723      |
| TAFINLAR 75 MG CAPSULE   | 34724      |
| TARGRETIN 75 MG CAPSULE  | 92373      |
| TEGRETOL 100 MG/5 ML SUSP                                      | 47500      |
| TEGRETOL 200 MG TABLET   | 17450      |
| TEGRETOL XR 100 MG TABLET                                      | 27820      |
| TEGRETOL XR 200 MG TABLET                                      | 27821      |
| TEGRETOL XR 400 MG TABLET                                      | 27822      |
| TRACLEER 125 MG TABLET   | 14978      |
| TRACLEER 32 MG TABLET FOR SUSP                                 | 43819      |
| TRACLEER 62.5 MG TABLET  | 14979      |
| XTANDI 40 MG CAPSULE   | 33183      |
| ZEBUTAL 50-325-40 MG CAPSULE                                   | 72510      |

| <b>Step 6 (Maximum Recommended Adjusted Dosing)</b> |   |
|---|---|
| Severe Hepatic Impairment (Child Pugh C)            | <p>≥ 12 years: 1,000mg daily</p> <p>≥ 4 to &lt; 12 years and ≥ 40kg: 1,000mg (two 500mg tablets) or 900mg (three 300mg tablets for oral suspension) daily</p> <p>≥ 4 to &lt; 12 years and 20kg to &lt; 40kg: 600mg daily</p> <p>≥ 4 to &lt; 12 years and 10kg to &lt; 20kg: 300mg daily</p> |

| <b>Step 6 (Maximum Recommended Adjusted Dosing)</b> |   |
|---|---|
| Concomitant use with strong CYP3A4 inducers         | <p>≥ 12 years: 2,500mg daily</p> <p>≥ 4 to &lt; 12 years and ≥ 40kg: 2,500mg five 500mg tablets) or 2,400mg (eight 300mg tablets for oral suspension) daily</p> <p>≥ 4 to &lt; 12 years and 20kg to &lt; 40kg: 1,500mg daily</p> <p>≥ 4 to &lt; 12 years and 10kg to &lt; 20kg: 900mg daily</p> |
| Concomitant use with moderate CYP3A4 inducers       | <p>≥ 12 years: 2,000mg daily</p> <p>≥ 4 to &lt; 12 years and ≥ 40kg: 2,000mg four 500mg tablets) or 2,100mg (seven 300mg tablets for oral suspension) daily</p> <p>≥ 4 to &lt; 12 years and 20kg to &lt; 40kg: 1,200mg daily</p> <p>≥ 4 to &lt; 12 years and 10kg to &lt; 20kg: 900mg daily</p> |

| <b>Step 7 (Maximum Recommended Dosing)</b> |  |
|--|--|
| Recommended dosing                         | <p>≥ 12 years: 1,500mg daily</p> <p>≥ 4 to &lt; 12 years and ≥ 40kg: 1,500mg daily</p> <p>≥ 4 to &lt; 12 years and 20kg to &lt; 40kg: 900mg daily</p> <p>≥ 4 to &lt; 12 years and 10kg to &lt; 20kg: 600mg daily</p> |



## Sickle Cell Disease Agents

### Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier / Gold Standard, Inc. 2023. Available at [www.clinicalpharmacology.com](http://www.clinicalpharmacology.com). Accessed on August 18, 2023.
2. Oxbryta Prescribing Information. South San Francisco, CA. Pfizer, Inc. August 2023.
3. Food and Drug Administration (FDA). Drug Development and Drug Interactions: Table of Substrates, Inhibitors and Inducers. December 2019. Available at [www.fda.gov](http://www.fda.gov).
4. Micromedex [online database]. Available at [www.micromedexsolutions.com](http://www.micromedexsolutions.com). Accessed on August 18, 2023.
5. Vichinsky. Disease-modifying therapies to prevent pain and other complications of sickle cell disease. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on August 18, 2023.)

## Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

| Publication Date | Notes  |
|------------------|--|
| 01/24/2020       | Initial publication and presentation to DUR Board  |
| 01/30/2020       | Updated Table 2 (removed ICD-10 code for sickle cell trait)  |
| 12/20/2021       | Updated age to $\geq 4$ years for Oxbryta<br>Removed check for strong CYP3A4 inhibitors/fluconazole (warning removed from prescribing information)<br>Added pediatric dosing information<br>Updated references |
| 02/17/2022       | Added GCN for Oxbryta 300 mg tablet for suspension (51717)<br>Updated Table 6 (maximum recommended adjusted dosage)  |
| 10/19/2022       | Annual review by staff<br>Added GCN for Zortress (28589) to Table 4 and Efavirenz (43301) to Table 5<br>Updated references   |
| 05/14/2024       | Annual review by staff<br>Updated references   |
| 06/10/2024       | Added GCN for Oxbryta (53456) to PA drug table   |