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

Criteria will be retired 10/17/2024 due to product recall

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.

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

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Clinical Criteria Logic

1. Is the client greater than or equal to (≥) 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)

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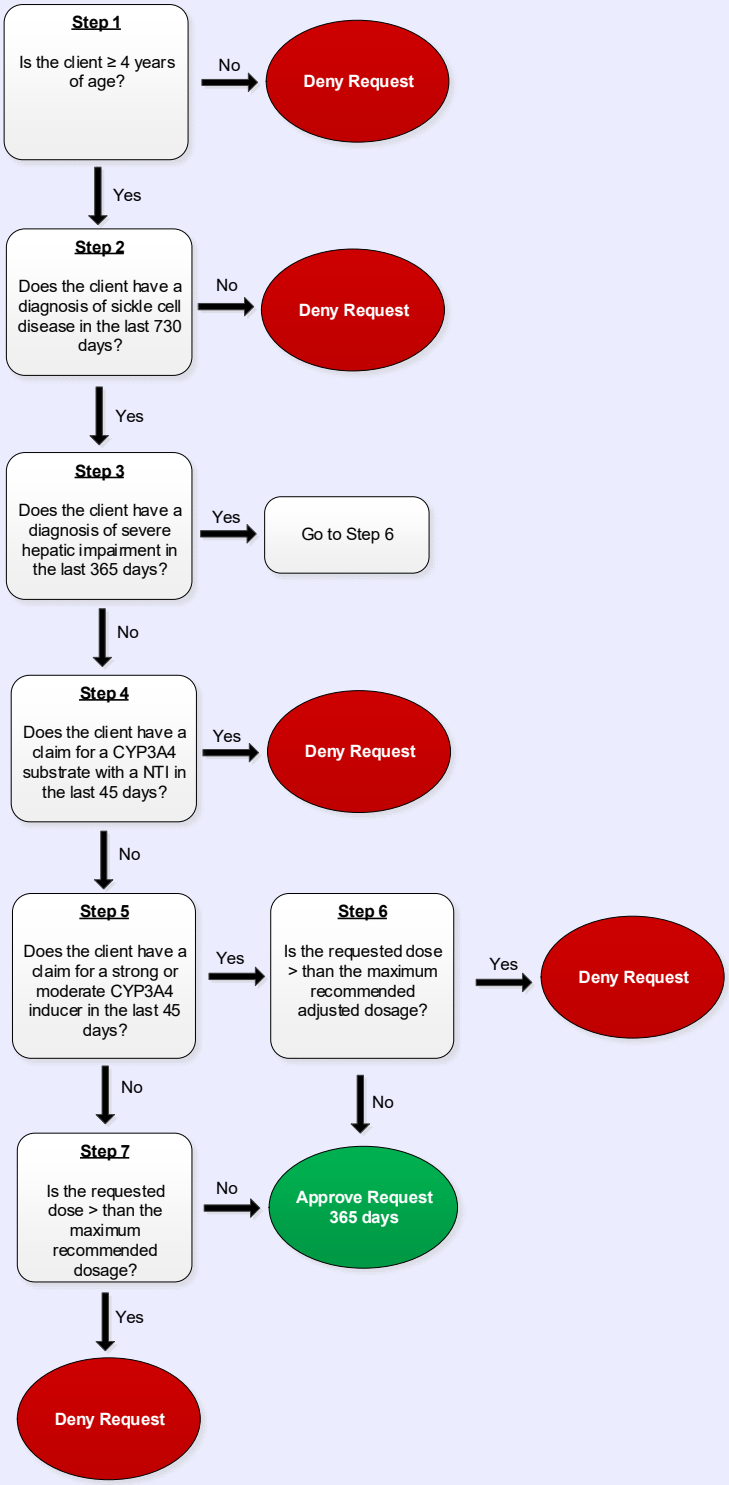
Clinical Criteria Logic Diagram



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Clinical Criteria Supporting Tables

Step 2 (diagnosis of sickle cell disease) Required diagnosis: *1* Look back timeframe: *730 days*	
ICD-10 Code	**Description**
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

Step 3 (diagnosis of severe hepatic impairment) Required diagnosis: *1* Look back timeframe: *365 days*	
ICD-10 Code	**Description**
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	UNSPECIFIFED 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

Step 3 (diagnosis of severe hepatic impairment) **Required diagnosis:** *1* **Look back timeframe:** *365 days*	
ICD-10 Code	**Description**
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

Step 3 (diagnosis of severe hepatic impairment) **Required diagnosis:** *1* **Look back timeframe:** *365 days*	
ICD-10 Code	**Description**
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

Step 4 (history of a CYP3A4 substrate with a NTI) **Number of claims:** *1* **Look back timeframe:** *45 days*	
Label Name	**GCN**
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
ENVARSUS XR 0.75 MG TABLET	39120
ENVARSUS XR 1 MG TABLET	39123
ENVARSUS 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

Step 4 (history of a CYP3A4 substrate with a NTI) **Number of claims:** *1* **Look back timeframe:** *45 days*	
Label Name	**GCN**
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

Step 5 (history of a strong or moderate CYP3A4 inducer) **Number of claims:** *1* **Look back timeframe:** *45 days*	
Label Name	**GCN**
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

Step 5 (history of a strong or moderate CYP3A4 inducer) **Number of claims:** *1* **Look back timeframe:** *45 days*	
Label Name	**GCN**
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

Step 5 (history of a strong or moderate CYP3A4 inducer) **Number of claims:** *1* **Look back timeframe:** *45 days*	
Label Name	**GCN**
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

Step 5 (history of a strong or moderate CYP3A4 inducer) **Number of claims:** *1* **Look back timeframe:** *45 days*	
Label Name	**GCN**
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

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

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

Step 7 (Maximum Recommended Dosing)	
Recommended dosing	≥ 12 years: 1,500mg daily ≥ 4 to < 12 years and ≥ 40kg: 1,500mg daily ≥ 4 to < 12 years and 20kg to < 40kg: 900mg daily ≥ 4 to < 12 years and 10kg to < 20kg: 600mg daily

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Sickle Cell Disease Agents

Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier / Gold Standard, Inc. 2023. Available at **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**.

4. Micromedex [online database]. Available at 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 ≥ 4 years for Oxbryta Removed check for strong CYP3A4 inhibitors/fluconazole (warning removed from prescribing information) Added pediatric dosing information Updated references
02/17/2022	Added GCN for Oxbryta 300 mg tablet for suspension (51717) Updated Table 6 (maximum recommended adjusted dosage)
10/19/2022	Annual review by staff Added GCN for Zortress (28589) to Table 4 and Efavirenz (43301) to Table 5 Updated references
05/14/2024	Annual review by staff Updated references
06/10/2024	Added GCN for Oxbryta (53456) to PA drug table
10/11/2024	Criteria will be retired 10/17/2024 due to product recall

