

**Texas Prior Authorization Program
Clinical Criteria**

Daybue (Trofinetide)

Clinical Criteria Information Included in this Document

Daybue (Trofinetide)

- **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

Initial publication and presentation for the DUR Board



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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
DAYBUE 200 MG/ML SOLUTION	53839



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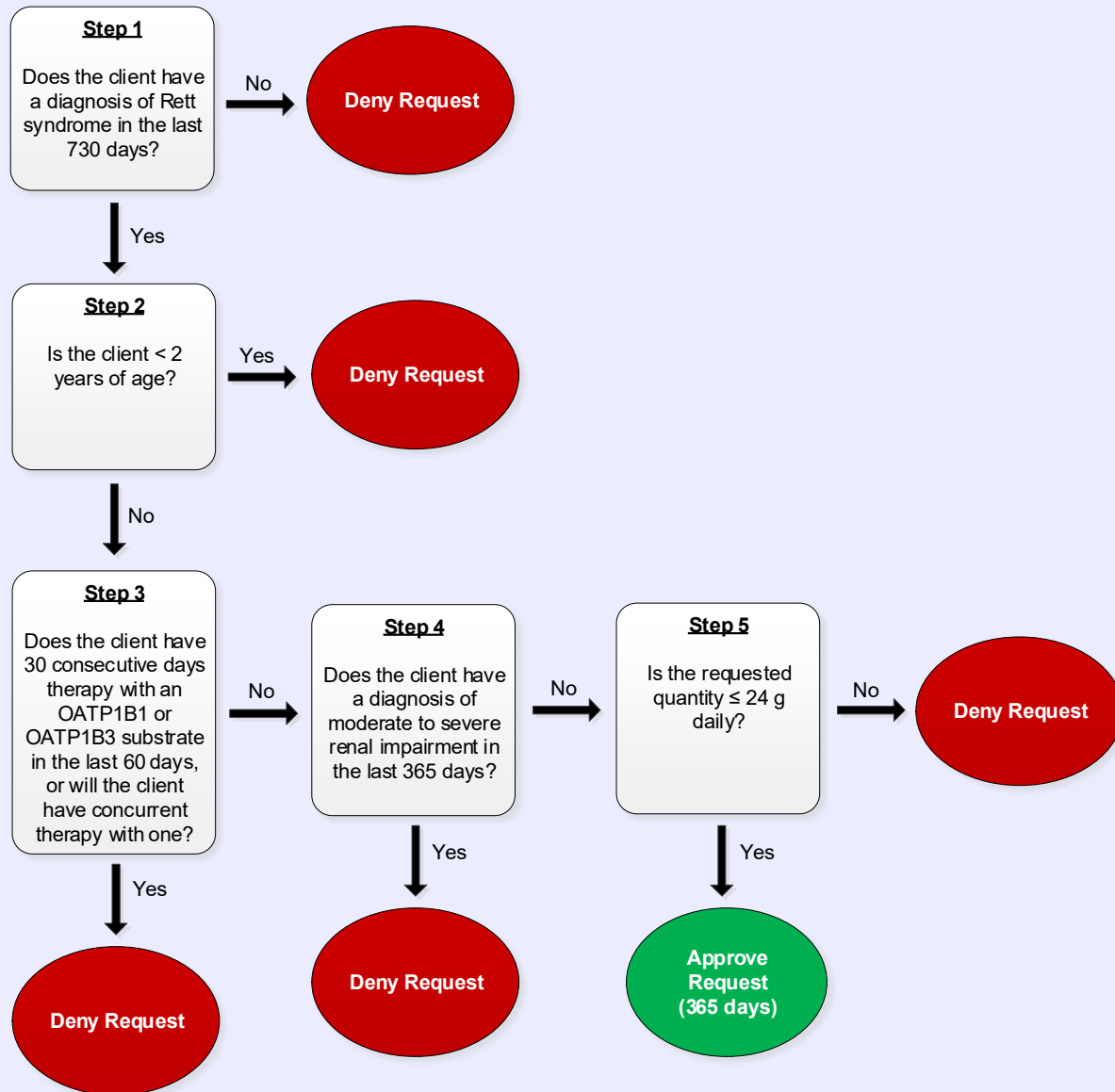
Clinical Criteria Logic

1. Does the client have a diagnosis of **Rett syndrome** in the last 730 days?
 Yes – Go to #2
 No – Deny
2. Is the client less than (<) 2 years of age?
 Yes – Deny
 No – Go to #3
3. Does the client have 30 consecutive days therapy with an **OATP1B1 or OATP1B3 substrate** in the last 60 days, or will the client have concurrent therapy with one?
 Yes – Deny
 No – Go to #4
4. Does the client have a diagnosis of **moderate or severe renal impairment** in the last 365 days?
 Yes – Deny
 No – Go to #5
5. Is the requested quantity less than or equal to (\leq) 24 g daily?
 Yes – Approve (365 days)
 No – Deny



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Clinical Criteria Logic Diagram





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Clinical Criteria Supporting Tables

Step 1 (diagnosis of Rett syndrome) Required quantity: 1 Look back timeframe: 730 days	
ICD-10 Code	Description
F842	RETT SYNDROME

Step 3 (OATP1B1/OATP1B3 substrate) Required quantity: 1 Look back timeframe: 60 days	
Label Name	GCN
ALLERGY RELIEF 180 MG TABLET	46594
ALLERGY RLF (FEXO) 60 MG TAB	46593
ALLERGY-CONGES 12HR 60-120 MG	63565
AMLODIPINE-ATORVAST 10-10 MG	21395
AMLODIPINE-ATORVAST 10-20 MG	21396
AMLODIPINE-ATORVAST 10-40 MG	21397
AMLODIPINE-ATORVAST 10-80 MG	21398
AMLODIPINE-ATORVAST 2.5-10 MG	23866
AMLODIPINE-ATORVAST 2.5-20 MG	23867
AMLODIPINE-ATORVAST 2.5-40 MG	23868
AMLODIPINE-ATORVAST 5-10 MG	21391
AMLODIPINE-ATORVAST 5-20 MG	21392
AMLODIPINE-ATORVAST 5-40 MG	21393
AMLODIPINE-ATORVAST 5-80 MG	21394
AMLODIPINE-OLMESARTAN 10-20 MG	98937
AMLODIPINE-OLMESARTAN 10-40 MG	98939
AMLODIPINE-OLMESARTAN 5-20 MG	98936
AMLODIPINE-OLMESARTAN 5-40 MG	98938
AMLODIPINE-VALSARTAN 10-160 MG	97963
AMLODIPINE-VALSARTAN 10-320 MG	98580
AMLODIPINE-VALSARTAN 5-160 MG	97962
AMLODIPINE-VALSARTAN 5-320 MG	98579
AMLOD-VALSA-HCTZ 10-160-12.5MG	22631
AMLOD-VALSA-HCTZ 10-160-25 MG	22649
AMLOD-VALSA-HCTZ 10-320-25 MG	22705

Step 3 (OATP1B1/OATP1B3 substrate)	
Required quantity: 1	
Look back timeframe: 60 days	
Label Name	GCN
AMLOD-VALSA-HCTZ 5-160-12.5 MG	22625
AMLOD-VALSA-HCTZ 5-160-25 MG	22648
ATORVASTATIN 10 MG TABLET	43720
ATORVASTATIN 20 MG TABLET	43721
ATORVASTATIN 40 MG TABLET	43722
ATORVASTATIN 80 MG TABLET	43723
AZOR 10-20 MG TABLET	98937
AZOR 10-40 MG TABLET	98939
AZOR 5-20 MG TABLET	98936
AZOR 5-40 MG TABLET	98938
BENICAR 20 MG TABLET	17285
BENICAR 40 MG TABLET	17286
BENICAR 5 MG TABLET	17284
BENICAR HCT 20-12.5 MG TABLET	20074
BENICAR HCT 40-12.5 MG TABLET	20075
BENICAR HCT 40-25 MG TABLET	20076
BOSENTAN 125 MG TABLET	14978
BOSENTAN 62.5 MG TABLET	14979
CADUET 10 MG-20 MG TABLET	21396
CADUET 10 MG-40 MG TABLET	21397
CADUET 10 MG-80 MG TABLET	21398
CADUET 5 MG-10 MG TABLET	21391
CADUET 5 MG-20 MG TABLET	21392
CADUET 5 MG-40 MG TABLET	21393
CADUET 5 MG-80 MG TABLET	21394
CEFADROXIL 1 GM TABLET	45345
CEFADROXIL 250 MG/5 ML SUSP	45343
CEFADROXIL 500 MG CAPSULE	45341
CEFADROXIL 500 MG/5 ML SUSP	45344
CEPHALEXIN 125 MG/5 ML SUSP	39811
CEPHALEXIN 250 MG CAPSULE	39801
CEPHALEXIN 250 MG TABLET	39832
CEPHALEXIN 250 MG/5 ML SUSP	39812
CEPHALEXIN 500 MG CAPSULE	39802
CEPHALEXIN 500 MG TABLET	39831
CEPHALEXIN 750 MG CAPSULE	27016
CRESTOR 10 MG TABLET	19153
CRESTOR 20 MG TABLET	19154

Step 3 (OATP1B1/OATP1B3 substrate)	
Required quantity: 1	
Look back timeframe: 60 days	
Label Name	GCN
CRESTOR 40 MG TABLET	19155
CRESTOR 5 MG TABLET	20229
DICLOFENAC POT 25 MG TABLET	13967
DICLOFENAC POT 50 MG TABLET	13960
DICLOFENAC POTASSIUM 25 MG CAP	27392
DICLOFENAC SOD EC 25 MG TAB	35850
DICLOFENAC SOD EC 50 MG TAB	35851
DICLOFENAC SOD EC 75 MG TAB	35852
DICLOFENAC SOD ER 100 MG TAB	13310
DICLOFENAC-MISOPROST 50-0.2 MG	62729
DICLOFENAC-MISOPROST 75-0.2 MG	06263
DIGOXIN 0.05 MG/ML SOLUTION	00120
DIGOXIN 125 MCG TABLET	00132
DIGOXIN 250 MCG TABLET	00133
DIGOXIN 62.5 MCG TABLET	00130
DIOVAN 160 MG TABLET	13844
DIOVAN 320 MG TABLET	13838
DIOVAN 40 MG TABLET	18092
DIOVAN 80 MG TABLET	13846
DIOVAN HCT 160-12.5 MG TAB	09760
DIOVAN HCT 160-25 MG TABLET	17245
DIOVAN HCT 320-12.5 MG TAB	27015
DIOVAN HCT 320-25 MG TABLET	27014
DIOVAN HCT 80-12.5 MG TABLET	07833
DROXIA 200 MG CAPSULE	38402
DROXIA 300 MG CAPSULE	38403
DROXIA 400 MG CAPSULE	38404
E.E.S. 200 MG/5 ML SUSPENSION	40523
ENALAPRIL 1 MG/ML ORAL SOLN	42337
ENALAPRIL MALEATE 10 MG TAB	00961
ENALAPRIL MALEATE 2.5 MG TAB	00963
ENALAPRIL MALEATE 20 MG TAB	00962
ENALAPRIL MALEATE 5 MG TABLET	00960
ENALAPRIL-HCTZ 10-25 MG TABLET	54860
ENALAPRIL-HCTZ 5-12.5 MG TAB	54862
ENTRESTO 24 MG-26 MG TABLET	39046
ENTRESTO 49 MG-51 MG TABLET	39047
ENTRESTO 97 MG-103 MG TABLET	39048

Step 3 (OATP1B1/OATP1B3 substrate)	
Required quantity: 1	
Look back timeframe: 60 days	
Label Name	GCN
EPANED 1 MG/ML ORAL SOLUTION	42337
ERYPED 200 MG/5 ML SUSPENSION	40523
ERYPED 400 MG/5 ML SUSPENSION	40524
ERYTHROCIN 500 MG ADDVAN VIAL	25529
ERYTHROCIN LACT 500 MG VIAL	40601
ERYTHROMYCIN 200 MG/5 ML SUSP	40523
ERYTHROMYCIN 250 MG TABLET	40720
ERYTHROMYCIN 400 MG/5 ML SUSP	40524
ERYTHROMYCIN 500 MG TABLET	40721
ERYTHROMYCIN DR 250 MG CAP	40660
ERYTHROMYCIN DR 250 MG TABLET	40730
ERYTHROMYCIN DR 333 MG TABLET	40731
ERYTHROMYCIN DR 500 MG TABLET	40732
ERYTHROMYCIN ES 400 MG TAB	40560
EXFORGE 10-160 MG TABLET	97963
EXFORGE 10-320 MG TABLET	98580
EXFORGE 5-160 MG TABLET	97962
EXFORGE 5-320 MG TABLET	98579
EZETIMIBE 10 MG TABLET	18387
EZETIMIBE-SIMVASTATIN 10-10 MG	23121
EZETIMIBE-SIMVASTATIN 10-20 MG	23125
EZETIMIBE-SIMVASTATIN 10-40 MG	23127
EZETIMIBE-SIMVASTATIN 10-80 MG	23126
FEXOFENADINE HCL 180 MG TABLET	46594
FEXOFENADINE HCL 60 MG TABLET	46593
FEXOFENADINE-PSE ER 60-120 TAB	63565
FLUVASTATIN ER 80 MG TABLET	89424
FLUVASTATIN SODIUM 20 MG CAP	00030
FLUVASTATIN SODIUM 40 MG CAP	00031
GLEEVEC 100 MG TABLET	19908
GLEEVEC 400 MG TABLET	19907
HYDREA 500 MG CAPSULE	38400
HYDROXYUREA 500 MG CAPSULE	38400
IMATINIB MESYLATE 100 MG TAB	19908
IMATINIB MESYLATE 400 MG TAB	19907
KALETRA 100-25 MG TABLET	99101
KALETRA 200-50 MG TABLET	25919
KALETRA 80 MG-20 MG/ML SOLN	31782

Step 3 (OATP1B1/OATP1B3 substrate)	
Required quantity: 1	
Look back timeframe: 60 days	
Label Name	GCN
LESCOL XL 80 MG TABLET	89424
LIPITOR 10 MG TABLET	43720
LIPITOR 20 MG TABLET	43721
LIPITOR 40 MG TABLET	43722
LIPITOR 80 MG TABLET	43723
LIVALO 1 MG TABLET	28588
LIVALO 2 MG TABLET	28594
LIVALO 4 MG TABLET	28595
LOFENA 25 MG TABLET	13967
LOPINAVIR-RITONAVIR 80-20MG/ML	31782
LOPINAVIR-RITONAVIR 100-25MG TB	99101
LOPINAVIR-RITONAVIR 200-50MG TB	25919
METHOTREXATE 2.5 MG TABLET	38489
METHOTREXATE 50 MG/2 ML VIAL	18936
METHOTREXATE 50 MG/2 ML VIAL	38466
MICARDIS 20 MG TABLET	23833
MICARDIS 40 MG TABLET	23831
MICARDIS 80 MG TABLET	23832
MICARDIS HCT 40-12.5 MG TABLET	12257
MICARDIS HCT 80-12.5 MG TABLET	12259
MICARDIS HCT 80-25 MG TABLET	22866
NEXLIZET 180-10 MG TABLET	47765
OLMESARTAN MEDOXOMIL 20 MG TAB	17285
OLMESARTAN MEDOXOMIL 40 MG TAB	17286
OLMESARTAN MEDOXOMIL 5 MG TAB	17284
OTREXUP 10 MG/0.4 ML AUTO-INJ	35427
OTREXUP 15 MG/0.4 ML AUTO-INJ	35428
OTREXUP 20 MG/0.4 ML AUTO-INJ	35437
OTREXUP 25 MG/0.4 ML AUTO-INJ	35438
PRAVASTATIN SODIUM 10 MG TAB	48671
PRAVASTATIN SODIUM 20 MG TAB	48672
PRAVASTATIN SODIUM 40 MG TAB	48673
PRAVASTATIN SODIUM 80 MG TAB	15412
PREZCOBIX 800 MG-150 MG TABLET	37367
PREZISTA 100 MG/ML SUSPENSION	31201
PREZISTA 150 MG TABLET	23489
PREZISTA 600 MG TABLET	99434
PREZISTA 75 MG TABLET	16759

Step 3 (OATP1B1/OATP1B3 substrate)	
Required quantity: 1	
Look back timeframe: 60 days	
Label Name	GCN
PREZISTA 800 MG TABLET	33723
RASUVO 10 MG/0.2 ML AUTOINJ	36847
RASUVO 12.5 MG/0.25 ML AUTOINJ	36848
RASUVO 15 MG/0.3 ML AUTOINJ	36849
RASUVO 17.5 MG/0.35 ML AUTOINJ	36851
RASUVO 20 MG/0.4 ML AUTOINJ	35437
RASUVO 22.5 MG/0.45 ML AUTOINJ	36852
RASUVO 25 MG/0.5 ML AUTOINJ	36853
RASUVO 30 MG/0.6 ML AUTOINJ	36855
RASUVO 7.5 MG/0.15 ML AUTOINJ	36846
ROSUVASTATIN CALCIUM 10 MG TAB	19153
ROSUVASTATIN CALCIUM 20 MG TAB	19154
ROSUVASTATIN CALCIUM 40 MG TAB	19155
ROSUVASTATIN CALCIUM 5 MG TAB	20229
SIKLOS 1,000 MG TABLET	44626
SIKLOS 100 MG TABLET	30164
SIMVASTATIN 10 MG TABLET	26532
SIMVASTATIN 20 MG TABLET	26533
SIMVASTATIN 40 MG TABLET	26534
SIMVASTATIN 5 MG TABLET	26531
SIMVASTATIN 80 MG TABLET	26535
SYMTUZA 800-150-200-10 MG TAB	43968
TELMISARTAN 20 MG TABLET	23833
TELMISARTAN 40 MG TABLET	23831
TELMISARTAN 80 MG TABLET	23832
TELMISARTAN-AMLODIPINE 40-10	27784
TELMISARTAN-AMLODIPINE 40-5 MG	27783
TELMISARTAN-AMLODIPINE 80-10	27786
TELMISARTAN-AMLODIPINE 80-5 MG	27785
TELMISARTAN-HCTZ 40-12.5 MG TB	12257
TELMISARTAN-HCTZ 80-12.5 MG TB	12259
TELMISARTAN-HCTZ 80-25 MG TAB	22866
TRACLEER 125 MG TABLET	14978
TRACLEER 32 MG TABLET FOR SUSP	43819
TRACLEER 62.5 MG TABLET	14979
TREXALL 10 MG TABLET	06484
TREXALL 15 MG TABLET	13135
TREXALL 5 MG TABLET	13134

Step 3 (OATP1B1/OATP1B3 substrate)	
Required quantity: 1	
Look back timeframe: 60 days	
Label Name	GCN
TREXALL 7.5 MG TABLET	38485
TRIBENZOR 20-5-12.5 MG TABLET	28837
TRIBENZOR 40-10-12.5 MG TABLET	28854
TRIBENZOR 40-10-25 MG TABLET	28855
TRIBENZOR 40-5-12.5 MG TABLET	28838
TRIBENZOR 40-5-25 MG TABLET	28839
VALSARTAN 160 MG TABLET	13844
VALSARTAN 320 MG TABLET	13838
VALSARTAN 40 MG TABLET	18092
VALSARTAN 80 MG TABLET	13846
VALSARTAN-HCTZ 160-12.5 MG TAB	09760
VALSARTAN-HCTZ 160-25 MG TAB	17245
VALSARTAN-HCTZ 320-12.5 MG TAB	27015
VALSARTAN-HCTZ 320-25 MG TAB	27014
VALSARTAN-HCTZ 80-12.5 MG TAB	07833
VASERETIC 10-25 MG TABLET	54860
VASOTEC 2.5 MG TABLET	00963
VYTORIN 10-10 MG TABLET	23121
VYTORIN 10-20 MG TABLET	23125
VYTORIN 10-40 MG TABLET	23127
VYTORIN 10-80 MG TABLET	23126
XATMEP 2.5 MG/ML ORAL SOLUTION	43319
ZETIA 10 MG TABLET	18387
ZOCOR 10 MG TABLET	26532
ZOCOR 20 MG TABLET	26533
ZOCOR 40 MG TABLET	26534
ZYPITAMAG 2 MG TABLET	43615
ZYPITAMAG 4 MG TABLET	43616

Step 4 (Diagnosis of moderate to severe renal impairment)	
Required quantity: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
N1830	CHRONIC KIDNEY DISEASE, STAGE 3 UNSPECIFIED (eGFR 59-30 mL/min)
N1831	CHRONIC KIDNEY DISEASE, STAGE 3A (eGFR 59-45 mL/min)
N1832	CHRONIC KIDNEY DISEASE, STAGE 3B (eGFR 44-30 mL/min)

Step 4 (Diagnosis of moderate to severe renal impairment)	
Required quantity: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
N184	CHRONIC KIDNEY DISEASE, STAGE 4 (SEVERE) (eGFR 29-15 mL/min)
N185	CHRONIC KIDNEY DISEASE, STAGE 5 (eGFR < 15 mL/min)
N186	END STAGE RENAL DISEASE



Daybue (Trofinetide)

Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2023. Available at www.clinicalpharmacology.com. Accessed on July 21, 2023.
2. 2023 ICD-10-CM Diagnosis Codes, Volume 1. 2023. Available at www.icd10data.com. Accessed on July 21, 2023.
3. Daybue Prescribing Information. San Diego, CA. Acadia Pharmaceuticals Inc. March 2023.



Daybue (Trofinetide)

Publication History

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
07/07/2023	Incorporated MCO suggestions for presentation
07/21/2023	Initial publication and presentation to the DUR Board