

Texas Prior Authorization Program
Clinical Criteria

Drug/Drug Class

Daybue (Trofinetide)

Clinical Criteria Information included in this Document

- [Drugs requiring prior authorization](#): the list of drugs requiring prior authorization for this clinical criterion
- [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); provided when applicable
- [References](#): clinical publications and sources relevant to this clinical criterion

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

Revision Notes

Added GCNs for Daybue Stix 5,000 mg packet (58663), Daybue Stix 6,000 mg packet (58664), and Daybue Stix 8,000 mg packet (58665) to the Drugs Requiring PA table



Daybue (Trofinetide)

Drugs Requiring Prior Authorization

The listed GCNs may not be an indication of Texas Medicaid Formulary coverage. To learn the current formulary coverage, visit txvendordrug.com/searches/formulary-drug-search.

Drugs Requiring Prior Authorization	
Label Name	GCN
DAYBUE STIX 5,000 MG PACKET	58663
DAYBUE STIX 6,000 MG PACKET	58664
DAYBUE STIX 8,000 MG PACKET	58665
DAYBUE 200 MG/ML SOLUTION	53839

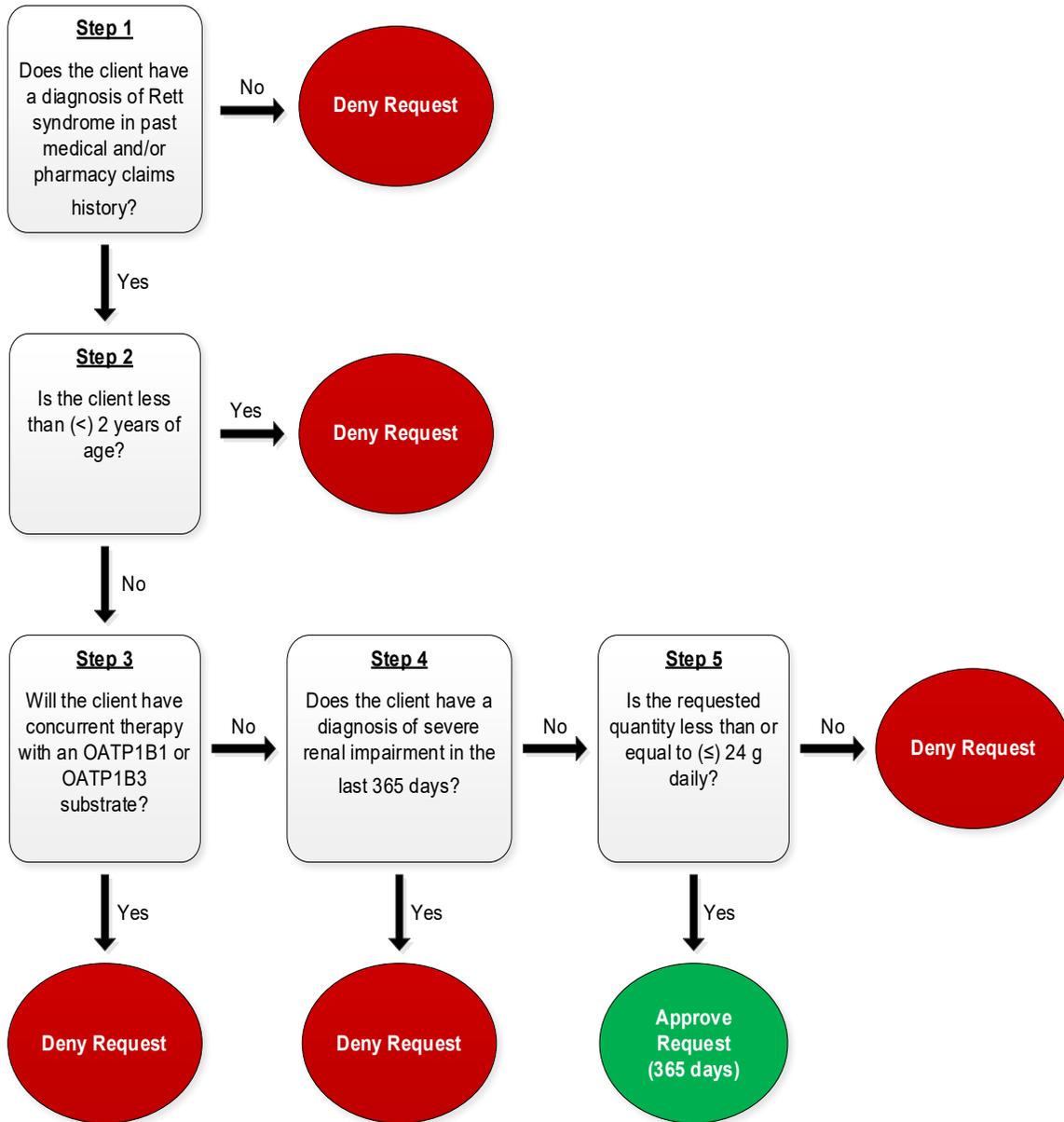


Daybue (Trofinetide) Clinical Criteria Logic

1. Does the client have a [diagnosis of Rett syndrome](#) in past medical and/or pharmacy claims history?
 Yes – Go to #2
 No – Deny
2. Is the client less than (<) 2 years of age?
 Yes – Deny
 No – Go to #3
3. Will the client have concurrent therapy with an [OATP1B1 or OATP1B3 substrate](#)?
 Yes – Deny
 No – Go to #4
4. Does the client have a [diagnosis of 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



Daybue (Trofinetide) Clinical Criteria Logic Diagram





Daybue (Trofinetide)

Clinical Criteria Supporting Tables

Table 1 (diagnosis of Rett syndrome)

ICD-10 Code	Description
F842	RETT'S SYNDROME

Table 3 (OATP1B1/OATP1B3 substrate)

GCN	Label Name
46594	ALLERGY RELIEF 180 MG TABLET
46593	ALLERGY RLF (FEXO) 60 MG TAB
63565	ALLERGY-CONGES 12HR 60-120 MG
21395	AMLODIPINE-ATORVAST 10-10 MG
21396	AMLODIPINE-ATORVAST 10-20 MG
21397	AMLODIPINE-ATORVAST 10-40 MG
21398	AMLODIPINE-ATORVAST 10-80 MG
23866	AMLODIPINE-ATORVAST 2.5-10 MG
23867	AMLODIPINE-ATORVAST 2.5-20 MG
23868	AMLODIPINE-ATORVAST 2.5-40 MG
21391	AMLODIPINE-ATORVAST 5-10 MG
21392	AMLODIPINE-ATORVAST 5-20 MG
21393	AMLODIPINE-ATORVAST 5-40 MG
21394	AMLODIPINE-ATORVAST 5-80 MG
98937	AMLODIPINE-OLMESARTAN 10-20 MG
98939	AMLODIPINE-OLMESARTAN 10-40 MG
98936	AMLODIPINE-OLMESARTAN 5-20 MG

Table 3 (OATP1B1/OATP1B3 substrate)	
GCN	Label Name
98938	AMLODIPINE-OLMESARTAN 5-40 MG
97963	AMLODIPINE-VALSARTAN 10-160 MG
98580	AMLODIPINE-VALSARTAN 10-320 MG
97962	AMLODIPINE-VALSARTAN 5-160 MG
98579	AMLODIPINE-VALSARTAN 5-320 MG
22631	AMLOD-VALSA-HCTZ 10-160-12.5MG
22649	AMLOD-VALSA-HCTZ 10-160-25 MG
22705	AMLOD-VALSA-HCTZ 10-320-25 MG
22625	AMLOD-VALSA-HCTZ 5-160-12.5 MG
22648	AMLOD-VALSA-HCTZ 5-160-25 MG
43720	ATORVASTATIN 10 MG TABLET
43721	ATORVASTATIN 20 MG TABLET
43722	ATORVASTATIN 40 MG TABLET
43723	ATORVASTATIN 80 MG TABLET
98937	AZOR 10-20 MG TABLET
98939	AZOR 10-40 MG TABLET
98936	AZOR 5-20 MG TABLET
98938	AZOR 5-40 MG TABLET
17285	BENICAR 20 MG TABLET
17286	BENICAR 40 MG TABLET
17284	BENICAR 5 MG TABLET
20074	BENICAR HCT 20-12.5 MG TABLET
20075	BENICAR HCT 40-12.5 MG TABLET
20076	BENICAR HCT 40-25 MG TABLET

Table 3 (OATP1B1/OATP1B3 substrate)	
GCN	Label Name
14978	BOSENTAN 125 MG TABLET
14979	BOSENTAN 62.5 MG TABLET
43819	BOSENTAN 32 MG TABLET FOR SUSP
23866	CADUET 2.5 MG-10 MG TABLET
23867	CADUET 2.5 MG-20 MG TABLET
23868	CADUET 2.5 MG-40 MG TABLET
21395	CADUET 10 MG-10 MG TABLET
21396	CADUET 10 MG-20 MG TABLET
21397	CADUET 10 MG-40 MG TABLET
21398	CADUET 10 MG-80 MG TABLET
21391	CADUET 5 MG-10 MG TABLET
21392	CADUET 5 MG-20 MG TABLET
21393	CADUET 5 MG-40 MG TABLET
21394	CADUET 5 MG-80 MG TABLET
45345	CEFADROXIL 1 GM TABLET
45343	CEFADROXIL 250 MG/5 ML SUSP
45341	CEFADROXIL 500 MG CAPSULE
45344	CEFADROXIL 500 MG/5 ML SUSP
39811	CEPHALEXIN 125 MG/5 ML SUSP
39801	CEPHALEXIN 250 MG CAPSULE
39832	CEPHALEXIN 250 MG TABLET
39812	CEPHALEXIN 250 MG/5 ML SUSP
39802	CEPHALEXIN 500 MG CAPSULE
39831	CEPHALEXIN 500 MG TABLET

Table 3 (OATP1B1/OATP1B3 substrate)	
GCN	Label Name
27016	CEPHALEXIN 750 MG CAPSULE
19153	CRESTOR 10 MG TABLET
19154	CRESTOR 20 MG TABLET
19155	CRESTOR 40 MG TABLET
20229	CRESTOR 5 MG TABLET
13967	DICLOFENAC POT 25 MG TABLET
13960	DICLOFENAC POT 50 MG TABLET
27392	DICLOFENAC POTASSIUM 25 MG CAP
35850	DICLOFENAC SOD EC 25 MG TAB
35851	DICLOFENAC SOD EC 50 MG TAB
35852	DICLOFENAC SOD EC 75 MG TAB
13310	DICLOFENAC SOD ER 100 MG TAB
62729	DICLOFENAC-MISOPROST 50-0.2 MG
06263	DICLOFENAC-MISOPROST 75-0.2 MG
00120	DIGOXIN 0.05 MG/ML SOLUTION
00132	DIGOXIN 125 MCG TABLET
00133	DIGOXIN 250 MCG TABLET
00130	DIGOXIN 62.5 MCG TABLET
13844	DIOVAN 160 MG TABLET
13838	DIOVAN 320 MG TABLET
18092	DIOVAN 40 MG TABLET
13846	DIOVAN 80 MG TABLET
09760	DIOVAN HCT 160-12.5 MG TAB
17245	DIOVAN HCT 160-25 MG TABLET

Table 3 (OATP1B1/OATP1B3 substrate)	
GCN	Label Name
27015	DIOVAN HCT 320-12.5 MG TAB
27014	DIOVAN HCT 320-25 MG TABLET
07833	DIOVAN HCT 80-12.5 MG TABLET
40523	E.E.S. 200 MG/5 ML SUSPENSION
42337	ENALAPRIL 1 MG/ML ORAL SOLN
00961	ENALAPRIL MALEATE 10 MG TAB
00963	ENALAPRIL MALEATE 2.5 MG TAB
00962	ENALAPRIL MALEATE 20 MG TAB
00960	ENALAPRIL MALEATE 5 MG TABLET
54860	ENALAPRIL-HCTZ 10-25 MG TABLET
54862	ENALAPRIL-HCTZ 5-12.5 MG TAB
39046	ENTRESTO 24 MG-26 MG TABLET
39047	ENTRESTO 49 MG-51 MG TABLET
39048	ENTRESTO 97 MG-103 MG TABLET
42337	EPANED 1 MG/ML ORAL SOLUTION
40523	ERYPED 200 MG/5 ML SUSPENSION
40524	ERYPED 400 MG/5 ML SUSPENSION
25529	ERYTHROCIN 500 MG ADDVAN VIAL
40601	ERYTHROCIN LACT 500 MG VIAL
40523	ERYTHROMYCIN 200 MG/5 ML SUSP
40720	ERYTHROMYCIN 250 MG TABLET
40524	ERYTHROMYCIN 400 MG/5 ML SUSP
40721	ERYTHROMYCIN 500 MG TABLET
40660	ERYTHROMYCIN DR 250 MG CAP

Table 3 (OATP1B1/OATP1B3 substrate)	
GCN	Label Name
40730	ERYTHROMYCIN DR 250 MG TABLET
40731	ERYTHROMYCIN DR 333 MG TABLET
40732	ERYTHROMYCIN DR 500 MG TABLET
40560	ERYTHROMYCIN ES 400 MG TAB
97963	EXFORGE 10-160 MG TABLET
98580	EXFORGE 10-320 MG TABLET
97962	EXFORGE 5-160 MG TABLET
98579	EXFORGE 5-320 MG TABLET
18387	EZETIMIBE 10 MG TABLET
23121	EZETIMIBE-SIMVASTATIN 10-10 MG
23125	EZETIMIBE-SIMVASTATIN 10-20 MG
23127	EZETIMIBE-SIMVASTATIN 10-40 MG
23126	EZETIMIBE-SIMVASTATIN 10-80 MG
46594	FEXOFENADINE HCL 180 MG TABLET
46593	FEXOFENADINE HCL 60 MG TABLET
37198	FEXOFENADINE HCL 30 MG TABLET
63565	FEXOFENADINE-PSE ER 60-120 TAB
89424	FLUVASTATIN ER 80 MG TABLET
00030	FLUVASTATIN SODIUM 20 MG CAP
00031	FLUVASTATIN SODIUM 40 MG CAP
19908	GLEEVEC 100 MG TABLET
19907	GLEEVEC 400 MG TABLET
38400	HYDREA 500 MG CAPSULE
38400	HYDROXYUREA 500 MG CAPSULE

Table 3 (OATP1B1/OATP1B3 substrate)	
GCN	Label Name
19908	IMATINIB MESYLATE 100 MG TAB
19907	IMATINIB MESYLATE 400 MG TAB
99101	KALETRA 100-25 MG TABLET
25919	KALETRA 200-50 MG TABLET
31782	KALETRA 80 MG-20 MG/ML SOLN
89424	LESCOL XL 80 MG TABLET
43720	LIPITOR 10 MG TABLET
43721	LIPITOR 20 MG TABLET
43722	LIPITOR 40 MG TABLET
43723	LIPITOR 80 MG TABLET
28588	LIVALO 1 MG TABLET
28594	LIVALO 2 MG TABLET
28595	LIVALO 4 MG TABLET
13967	LOFENA 25 MG TABLET
31782	LOPINAVIR-RITONAVIR 80-20MG/ML
99101	LOPINAVIR-RITONAVR 100-25MG TB
25919	LOPINAVIR-RITONAVR 200-50MG TB
38489	METHOTREXATE 2.5 MG TABLET
18936	METHOTREXATE 50 MG/2 ML VIAL
38466	METHOTREXATE 50 MG/2 ML VIAL
23831	MICARDIS 40 MG TABLET
12257	MICARDIS HCT 40-12.5 MG TABLET
12259	MICARDIS HCT 80-12.5 MG TABLET
22866	MICARDIS HCT 80-25 MG TABLET

Table 3 (OATP1B1/OATP1B3 substrate)	
GCN	Label Name
47765	NEXLIZET 180-10 MG TABLET
17285	OLMESARTAN MEDOXOMIL 20 MG TAB
17286	OLMESARTAN MEDOXOMIL 40 MG TAB
17284	OLMESARTAN MEDOXOMIL 5 MG TAB
20074	OLMESARTAN-HCTZ 20-12.5 MG TAB
20075	OLMESARTAN-HCTZ 40-12.5 MG TAB
20076	OLMESARTAN-HCTZ 40-25 MG TAB
28837	OLMSRTN-AMLDPN-HCTZ 20-5-12.5
28854	OLMSRTN-AMLDPN-HCTZ 40-10-12.5
28855	OLMSRTN-AMLDPN-HCTZ 40-10-25MG
28838	OLMSRTN-AMLDPN-HCTZ 40-5-12.5
28839	OLMSRTN-AMLDPN-HCTZ 40-5-25 MG
48671	PRAVASTATIN SODIUM 10 MG TAB
48672	PRAVASTATIN SODIUM 20 MG TAB
48673	PRAVASTATIN SODIUM 40 MG TAB
15412	PRAVASTATIN SODIUM 80 MG TAB
58213	PREZCOBIX 675 MG-150 MG TABLET
37367	PREZCOBIX 800 MG-150 MG TABLET
31201	PREZISTA 100 MG/ML SUSPENSION
23489	PREZISTA 150 MG TABLET
99434	PREZISTA 600 MG TABLET
16759	PREZISTA 75 MG TABLET
33723	PREZISTA 800 MG TABLET
36847	RASUVO 10 MG/0.2 ML AUTOINJ

Table 3 (OATP1B1/OATP1B3 substrate)	
GCN	Label Name
36848	RASUVO 12.5 MG/0.25 ML AUTOINJ
36849	RASUVO 15 MG/0.3 ML AUTOINJ
36851	RASUVO 17.5 MG/0.35 ML AUTOINJ
35437	RASUVO 20 MG/0.4 ML AUTOINJ
36852	RASUVO 22.5 MG/0.45 ML AUTOINJ
36853	RASUVO 25 MG/0.5 ML AUTOINJ
36855	RASUVO 30 MG/0.6 ML AUTOINJ
36846	RASUVO 7.5 MG/0.15 ML AUTOINJ
19153	ROSUVASTATIN CALCIUM 10 MG TAB
19154	ROSUVASTATIN CALCIUM 20 MG TAB
19155	ROSUVASTATIN CALCIUM 40 MG TAB
20229	ROSUVASTATIN CALCIUM 5 MG TAB
44626	SIKLOS 1,000 MG TABLET
30164	SIKLOS 100 MG TABLET
26532	SIMVASTATIN 10 MG TABLET
26533	SIMVASTATIN 20 MG TABLET
26534	SIMVASTATIN 40 MG TABLET
26531	SIMVASTATIN 5 MG TABLET
26535	SIMVASTATIN 80 MG TABLET
43968	SYMTUZA 800-150-200-10 MG TAB
23833	TELMISARTAN 20 MG TABLET
23831	TELMISARTAN 40 MG TABLET
23832	TELMISARTAN 80 MG TABLET
27784	TELMISARTAN-AMLODIPINE 40-10

Table 3 (OATP1B1/OATP1B3 substrate)	
GCN	Label Name
27783	TELMISARTAN-AMLODIPINE 40-5 MG
27786	TELMISARTAN-AMLODIPINE 80-10
27785	TELMISARTAN-AMLODIPINE 80-5 MG
12257	TELMISARTAN-HCTZ 40-12.5 MG TB
12259	TELMISARTAN-HCTZ 80-12.5 MG TB
22866	TELMISARTAN-HCTZ 80-25 MG TAB
14978	TRACLEER 125 MG TABLET
43819	TRACLEER 32 MG TABLET FOR SUSP
14979	TRACLEER 62.5 MG TABLET
06484	TREXALL 10 MG TABLET
13135	TREXALL 15 MG TABLET
13134	TREXALL 5 MG TABLET
38485	TREXALL 7.5 MG TABLET
28837	TRIBENZOR 20-5-12.5 MG TABLET
28854	TRIBENZOR 40-10-12.5 MG TABLET
28855	TRIBENZOR 40-10-25 MG TABLET
28838	TRIBENZOR 40-5-12.5 MG TABLET
28839	TRIBENZOR 40-5-25 MG TABLET
13844	VALSARTAN 160 MG TABLET
13838	VALSARTAN 320 MG TABLET
18092	VALSARTAN 40 MG TABLET
13846	VALSARTAN 80 MG TABLET
09760	VALSARTAN-HCTZ 160-12.5 MG TAB
17245	VALSARTAN-HCTZ 160-25 MG TAB

Table 3 (OATP1B1/OATP1B3 substrate)	
GCN	Label Name
27015	VALSARTAN-HCTZ 320-12.5 MG TAB
27014	VALSARTAN-HCTZ 320-25 MG TAB
07833	VALSARTAN-HCTZ 80-12.5 MG TAB
54860	VASERETIC 10-25 MG TABLET
54862	VASERETIC 5-12.5 MG TABLET
00960	VASOTEC 5 MG TABLET
00961	VASOTEC 10 MG TABLET
00962	VASOTEC 20 MG TABLET
00963	VASOTEC 2.5 MG TABLET
23121	VYTORIN 10-10 MG TABLET
23125	VYTORIN 10-20 MG TABLET
23127	VYTORIN 10-40 MG TABLET
23126	VYTORIN 10-80 MG TABLET
43319	XATMEP 2.5 MG/ML ORAL SOLUTION
18387	ZETIA 10 MG TABLET
26531	ZOCOR 5 MG TABLET
26532	ZOCOR 10 MG TABLET
26533	ZOCOR 20 MG TABLET
26534	ZOCOR 40 MG TABLET
43615	ZYPITAMAG 2 MG TABLET
43616	ZYPITAMAG 4 MG TABLET

Table 4 (diagnosis of severe renal impairment)	
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.; 2025. Available at www.clinicalkey.com/pharmacology. Accessed on October 29, 2025.
2. 2025 ICD-10-CM Diagnosis Codes, Volume 1. 2025. Available at www.icd10data.com. Accessed on October 29, 2025.
3. Daybue Prescribing Information. San Diego, CA. Acadia Pharmaceuticals Inc. August 2025.



Daybue (Trofinetide)

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	<ul style="list-style-type: none"> Incorporated MCO suggestions for presentation
07/21/2023	<ul style="list-style-type: none"> Initial publication and presentation to the DUR Board
11/12/2024	<ul style="list-style-type: none"> Updated question 4 in logic and diagram to severe renal impairment (less than 30 mL/min)
01/24/2025	<ul style="list-style-type: none"> Annual review by staff Updated references
10/31/2025	<ul style="list-style-type: none"> Annual review by staff Added GCNs for Bosentan (43819), Caduet (23866, 23867, 23868, 21395), fexofenadine (37198), olmesartan-HCTZ (20074, 20075, 20076), olmesartan-amlodipine-HCTZ (28837, 28854, 28855, 28838, 28839), Prezcoibix (58213), Vasoretic (54862), Vasotec (00960, 00961, 00962), and Zocor (26531) to the OATP1B1/OATP1B3 Substrate supporting table Removed GCNs for Droxia (38404, 38403, 38402), Micardis (23833, 23832), and Otrexup (35438, 35437, 35428, 35427) from the OATP1B1/OATP1B3 Substrate supporting table – products discontinued Updated criteria lookback language to say, “in past medical and/or pharmacy claims history?” Updated check for prior claims of OATP1B1 or OATP1B3 substrates to check for concurrent therapy only Updated references
01/14/2026	<ul style="list-style-type: none"> Added GCNs for Daybue Stix 5,000 mg packet (58663), Daybue Stix 6,000 mg packet (58664), and Daybue Stix 8,000 mg packet (58665) to the Drugs Requiring PA table