

Texas Prior Authorization Program Clinical Criteria

Drug/Drug Class

Systemic Corticosteroids

This criteria was recommended for review by the Texas Medicaid Vendor Drug Program to ensure appropriate and safe utilization. Additional MCO recommendations have been incorporated.

Clinical Information Included in this Document

Emflaza/Agamree

- **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); provided when applicable
- **References:** clinical publications and sources relevant to this clinical criteria

Note: Click the hyperlink to navigate directly to that section

Revision Notes

Added criteria for Agamree as approved by the DUR Board



Systemic Corticosteroids

Drugs Requiring Prior Authorization

Drugs Requiring Prior Authorization	
Label Name	GCN
AGAMREE 40 MG/ML SUSPENSION	54925
EMFLAZA 18 MG TABLET	43012
EMFLAZA 22.75 MG/ML ORAL SUSP	43016
EMFLAZA 30 MG TABLET	23762
EMFLAZA 36 MG TABLET	43015
EMFLAZA 6 MG TABLET	23761



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Clinical Criteria Logic

Initial Requests:

1. Is the client greater than or equal to (\geq) 2 years of age?
 Yes (Go to #2)
 No (Deny)
2. Does the client have a **diagnosis of Duchenne muscular dystrophy (DMD)** in the last 730 days?
 Yes (Go to #3)
 No (Deny)
3. Has the client tried prednisone for greater than or equal to (\geq) 6 months, AND have one of the following adverse events as a result of prednisone use [Manual]:
 - a. Cushingoid appearance
 - b. Central (truncal) obesity
 - c. Undesirable weight gain (defined as greater than or equal to [\geq] 10% body weight gain over a 6-month period)
 - d. Diabetes and/or hypertension that is difficult to manage according to the prescribing physician
 - e. Inhibition of growth and/or concerning osteoporosis markers Yes (And the request is for Agamree, approve – 365 days)
 Yes (And the request is for Emflaza, go to #5)
 No (Go to #4)
4. Has the client experienced a severe behavioral adverse event while on prednisone therapy that has or will require a prednisone dose reduction [Manual]?
 Yes (And the request is for Agamree, approve – 365 days)
 Yes (And the request is for Emflaza – go to #5)
 No (Deny)
5. Does the client have a claim for a **moderate or strong CYP3A4 inducer** in the last 90 days?
 Yes (Deny)
 No (Approve – 365 days)

Renewal Requests:

1. Does the physician state that the client continues to have a positive response to therapy [Manual]?
 - Yes (And the request is for Agamree, approve – 365 days)
 - Yes (And the request is for Emflaza, go to #2)
 - No (Deny)

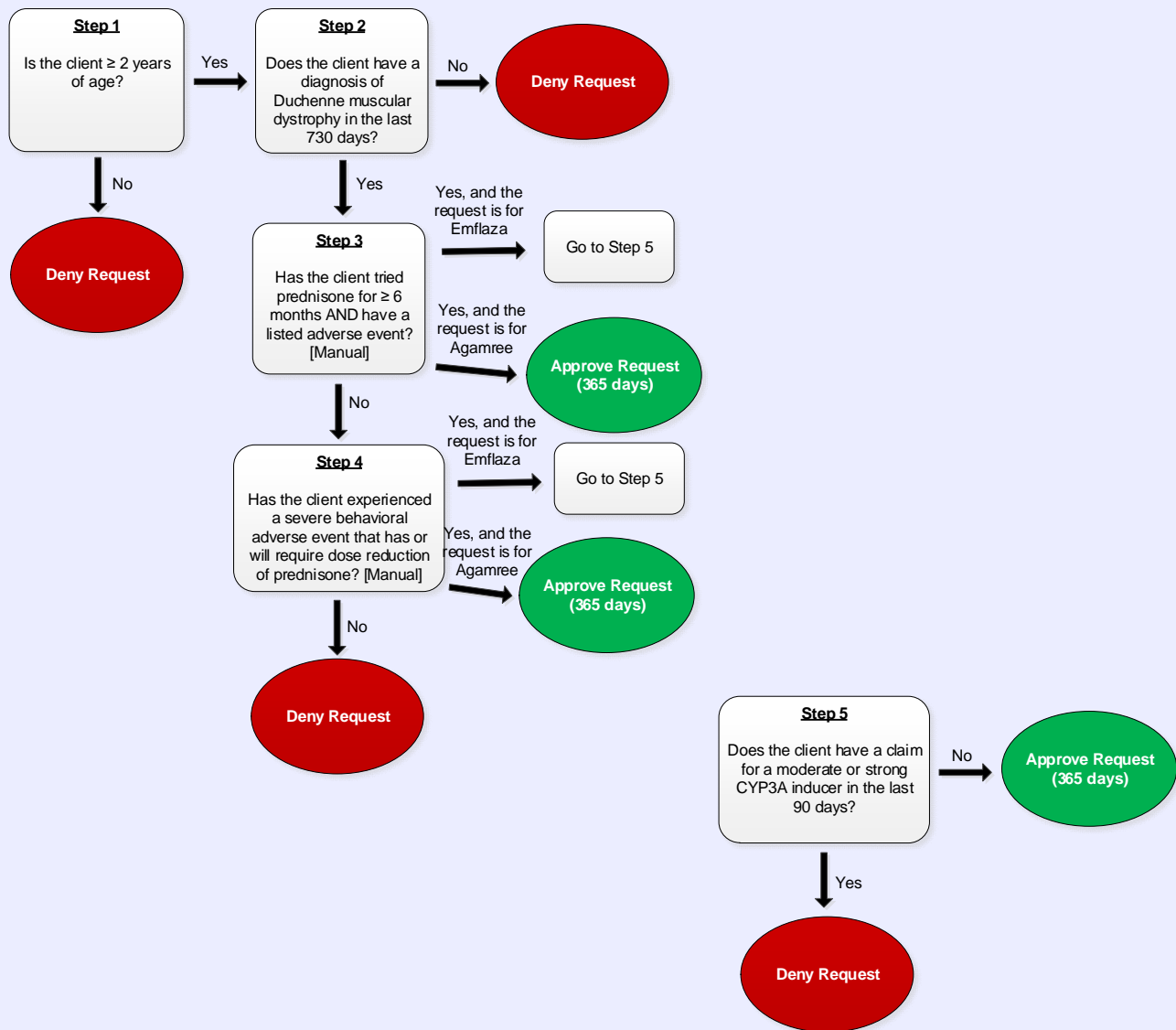
2. Does the client have a claim for a **moderate or strong CYP3A4 inducer** in the last 90 days?
 - Yes (Deny)
 - No (Approve – 365 days)



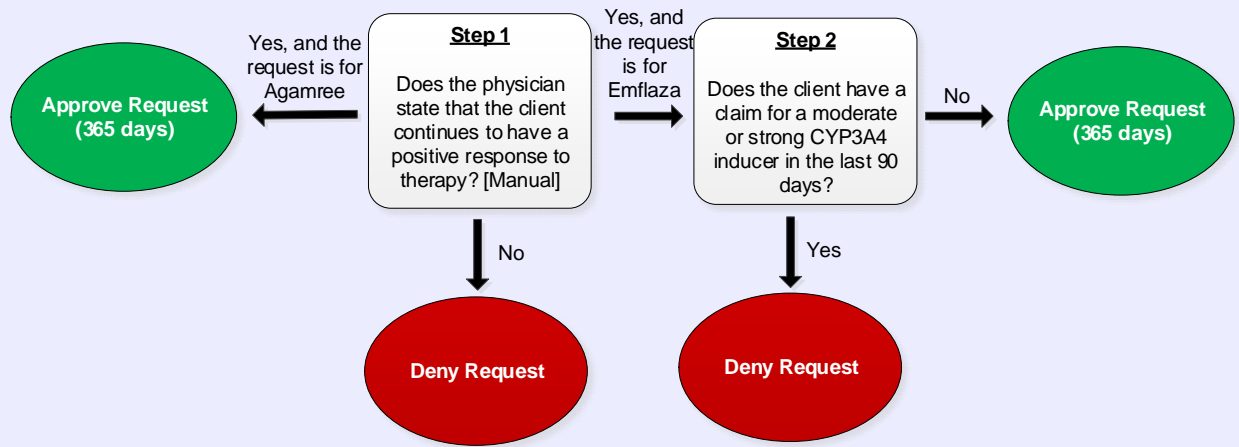
Systemic Corticosteroids

Clinical Criteria Logic Diagram

Initial Requests:



Renewal Requests:





Systemic Corticosteroids

Clinical Criteria Supporting Tables

Step 2 (diagnosis of Duchenne muscular dystrophy) Required diagnosis: 1 Look back timeframe: 730 days	
ICD-10 Code	Description
G710	MUSCULAR DYSTROPHY

Step 3a (claim for prednisone) Required days supply: 180 Look back timeframe: 200 days	
Label Name	GCN
PREDNISONE 1 MG TABLET	27171
PREDNISONE 10 MG TABLET	27172
PREDNISONE 2.5 MG TABLET	27173
PREDNISONE 20 MG TABLET	27174
PREDNISONE 5 MG TABLET	27176
PREDNISONE 5 MG/5 ML SOLUTION	27161
PREDNISONE 5 MG/5 ML SOLUTION	27160
PREDNISONE 50 MG TABLET	27177

Step 5 (claim for a moderate/strong CYP3A4 inducer) Required claims: 1 Look back timeframe: 90 days	
Label Name	GCN
ACTOPLUS MET 15-850MG TABLET	25445
ACTOPLUS MET 15-500MG TABLET	25444
ACTOPLUS MET XR 15-1000MG TABLET	28620
ACTOPLUS MET XR 30-1000MG TABLET	28622
ACTOS 15MG TABLET	92991
ACTOS 30MG TABLET	93001
ACTOS 45MG TABLET	93011
ALOGLIPTIN-PIOGLIT 12.5-15 MG	34080
ALOGLIPTIN-PIOGLIT 12.5-30 MG	34083

Step 5 (claim for a moderate/strong CYP3A4 inducer)	
Required claims: 1	
Look back timeframe: 90 days	
Label Name	GCN
ALOGLIPTIN-PIOGLIT 12.5-45 MG	34084
ALOGLIPTIN-PIOGLIT 25-15 MG TB	34077
ALOGLIPTIN-PIOGLIT 25-30 MG TB	34078
ALOGLIPTIN-PIOGLIT 25-45 MG TB	34079
APTIOM 200MG TABLET	36098
APTIOM 400MG TABLET	36099
APTIOM 600MG TABLET	36106
APTIOM 800MG TABLET	27409
ATRIPLA TABLET	27346
BEXAROTENE 75MG CAPSULE	92373
CARBAMAZEPINE 100 MG TAB CHEW	17460
CARBAMAZEPINE 100 MG/5 ML SUSP	47500
CARBAMAZEPINE 200 MG TABLET	17450
CARBAMAZEPINE ER 100 MG CAP	23934
CARBAMAZEPINE ER 200 MG CAP	23932
CARBAMAZEPINE ER 200 MG TABLET	27821
CARBAMAZEPINE ER 300 MG CAP	23933
CARBAMAZEPINE ER 400 MG TABLET	27822
CARBAMAZEPINE ER 100 MG TABLET	27820
CARBATROL ER 100 MG CAPSULE	23934
CARBATROL ER 200 MG CAPSULE	23932
CARBATROL ER 300 MG CAPSULE	23933
DILANTIN 100 MG CAPSULE	17700
DILANTIN 125 MG/5 ML SUSP	17241
DILANTIN 30 MG CAPSULE	17701
DILANTIN 50 MG INFATAB	17250
DUETACT 30-2MG TABLET	97181
DUETACT 30-4MG TABLET	97180
EPITOL 200 MG TABLET	17450
EQUETRO 100 MG CAPSULE	13781
EQUETRO 200 MG CAPSULE	13805
EQUETRO 300 MG CAPSULE	13818
INTELENCE 100MG TABLET	99318
INTELENCE 200MG TABLET	29424
INTELENCE 25MG TABLET	32035
LYSODREN 500MG TABLET	38710
MODAFINIL 100MG TABLET	26101
MODAFINIL 200MG TABLET	26102

Step 5 (claim for a moderate/strong CYP3A4 inducer)	
Required claims: 1	
Look back timeframe: 90 days	
Label Name	GCN
MYCOBUTIN 150 MG CAPSULE	29810
MYSOLINE 250 MG/5 ML SUSP	17310
MYSOLINE 250MG TABLET	17321
MYSOLINE 50MG TABLET	17322
NEVIRAPINE 200MG TABLET	31420
NEVIRAPINE 50MG/5ML SUSPENSION	31421
NEVIRAPINE ER 400MG TABLET	29767
NEVIRAPINE ER 100 MG TABLET	30935
ORKAMBI 100-125MG TABLET	42366
ORKAMBI 200-125MG TABLET	39008
ORKAMBI 100-125 MG GRANULE PKT	36937
ORKAMBI 150-188 MG GRANULE PKT	42848
ORKAMBI 75-94 MG GRANULE PKT	52865
OSENI 12.5-15MG TABLET	34080
OSENI 12.5-30MG TABLET	34083
OSENI 12.5-45MG TABLET	34084
OSENI 25-15MG TABLET	34077
OSENI 25-30MG TABLET	34078
OSENI 25-45MG TABLET	34079
PHENOBARBITAL 100 MG TABLET	12975
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

Step 5 (claim for a moderate/strong CYP3A4 inducer)	
Required claims: 1	
Look back timeframe: 90 days	
Label Name	GCN
PIOGLITAZONE HCL 15 MG TABLET	92991
PIOGLITAZONE HCL 30 MG TABLET	93001
PIOGLITAZONE HCL 45 MG TABLET	93011
PIOGLITAZONE-GLIMEPIRIDE 30-2	97181
PIOGLITAZONE-GLIMEPIRIDE 30-4	97180
PIOGLITAZONE-METFORMIN 15-500	25444
PIOGLITAZONE-METFORMIN 15-850	25445
PRIFTIN 150MG TABLET	45911
PRIMIDONE 250MG TABLET	17321
PRIMIDONE 50MG TABLET	17322
PROVIGIL 100MG TABLET	26101
PROVIGIL 200MG TABLET	26102
RIFABUTIN 150 MG CAPSULE	29810
RIFADIN 150 MG CAPSULE	41260
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 100 MG CAPSULE	43302
SUSTIVA 200MG CAPSULE	43303
SUSTIVA 50MG CAPSULE	43301
SUSTIVA 600MG TABLET	15555
TAFINLAR 50MG CAPSULE	34723
TAFINLAR 75MG CAPSULE	34724
TARGRETIN 75 MG SOFTGEL	92373
TARGRETIN 75MG CAPSULE	92373
TEGRETOL 100 MG TABLET CHEW	17460
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 125MG TABLET	14978
TRACLEER 62.5MG TABLET	14979
TRACLEER 32 MG TABLET FOR SUSP	43819

Step 5 (claim for a moderate/strong CYP3A4 inducer)	
Required claims: 1	
Look back timeframe: 90 days	
Label Name	GCN
VIRAMUNE 200MG TABLET	31420
VIRAMUNE 50MG/5ML SUSPENSION	31421
VIRAMUNE XR 100MG TABLET	30935
VIRAMUNE XR 400MG TABLET	29767
XTANDI 40MG CAPSULE	33183
XTANDI 40 MG TABLET	46626
XTANDI 80 MG TABLET	48452



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Clinical Criteria References

1. 2017 ICD-10-CM Diagnosis Codes. 2017. Available at www.icd10data.com. Accessed on July 28, 2017.
2. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2023. Available at www.clinicalpharmacology.com. Accessed on November 15, 2023.
3. Micromedex [online database]. 2023. Available at www.micromedexsolutions.com. Accessed on July 29, 2024.
4. Emflaza Prescribing Information. South Plainfield, NJ. PTC Therapeutics, Inc. June 2021.
5. Indiana University, Department of Medicine, Clinical Pharmacology Research Institute. P450 Interaction Table. Available at medicine.iupui.edu. Accessed on July 28, 2017.
6. U.S. Food and Drug Administration (FDA). Drug Development and Drug Interactions: Table of Substrates, Inhibitors and Inducers. Available at www.fda.gov. Accessed on December 9, 2020.
7. UpToDate. Cytochrome P450 3A4 Inhibitors and Inducers. Available at www.uptodate.com. Accessed on December 9, 2020.
8. Gloss D, Moxley RT, et al. Practice Guideline Update Summary: Corticosteroid Treatment of Duchenne Muscular Dystrophy Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology* Feb 2016, 86(5); 465-472.

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
07/28/2017	Initial publication and presentation to the DUR Board
03/28/2019	Updated to include formulary statement (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 .) on each 'Drug Requiring PA' table
07/03/2019	Updated age to 2 years and older on criteria logic and logic diagram Updated references
04/30/2021	Annual review by staff Added GCNs for alogliptin-pioglitazone (34080, 34083, 34084, 34077, 34078, 34079); carbamazepine ER (27820); Orkambi granules (36937, 42848); Tracleer suspension (43819) to Table 5 Updated references
10/07/2021	Removed specialist requirement from criteria
12/05/2023	Annual review by staff Updated references
09/18/2024	Annual review by staff Added GCNs for Mysoline (17310), Nevirapine (30935), Orkambi (52865), Sustiva (43302), Targretin (92373), Tegretol (17460), and Xtandi (46626, 48452) to the Supporting Tables section. Updated references
10/25/2024	Added criteria for Agamree as approved by the DUR Board