

Texas Prior Authorization Program Clinical Criteria

Drug/Drug Class

Pulmonary Hypertension Agents

This criteria was recommended for review by an MCO to ensure appropriate and safe utilization

Injectable PH Agents

- **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.

Oral/Inhaled PH Agents

- **Drugs requiring clinical prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Clinical 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

Annual review by staff

Updated references



Injectable Pulmonary Hypertension Agents

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.

Injectable Agents for the Treatment of PH	
Label Name	GCN
EOPROSTENOL SODIUM 0.5MG VIAL	56680
EOPROSTENOL SODIUM 1.5MG VIAL	56681
EOPROSTENOL SODIUM 0.5MG VIAL	33243
EOPROSTENOL SODIUM 1.5MG VIAL	30168
FLOLAN 0.5MG VIAL	56680
FLOLAN 1.5MG VIAL	56681
REMODULIN 10MG/ML VIAL	17436
REMODULIN 1MG/ML VIAL	17433
REMODULIN 2.5MG/ML VIAL	17434
REMODULIN 5MG/ML VIAL	17435
TREPROSTINIL 100MG/20ML VIAL	17435
TREPROSTINIL 200MG/20ML VIAL	17436
TREPROSTINIL 20MG/20ML VIAL	17433
TREPROSTINIL 50MG/20ML VIAL	17434
VELETRI 0.5MG VIAL	33243
VELETRI 1.5MG VIAL	30168



Injectable Pulmonary Hypertension Agents

Clinical Criteria Logic

1. Does the client have a **diagnosis of pulmonary arterial hypertension** in the last 730 days?
 Yes – Go to #2
 No – Deny

2. Has the diagnosis been confirmed by or does the client have a contraindication to right heart catheterization? [manual]
 Yes – Go to #3
 No – Deny

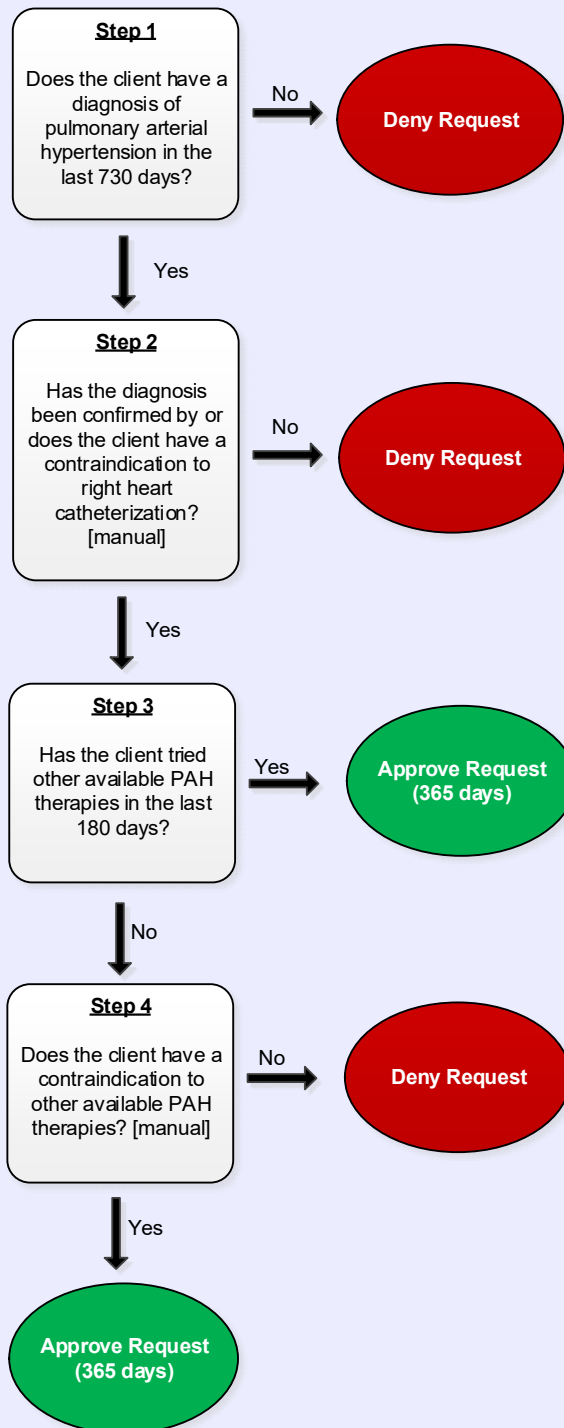
3. Has the client tried other available **PAH therapies** in the last 180 days?
 Yes – Approve (365 days)
 No – Go to #4

4. Does the client have a contraindication to other available PAH therapies? [manual]
 Yes – Approve (365 days)
 No – Deny



Injectable Pulmonary Hypertension Agents

Clinical Criteria Logic Diagram





Injectable Pulmonary Hypertension Agents

Clinical Criteria Supporting Tables

Step 1 (diagnosis of Pulmonary Hypertension)	
Required quantity: 1	
Look back timeframe: 730 days	
ICD-10 Code	Description
I270	PRIMARY PULMONARY HYPERTENSION

Step 3 (claim for alternate therapy)	
Required quantity: 1	
Look back timeframe: 730 days	
GCN	Label Name
02226	ADALAT CC 30MG TABLET
02227	ADALAT CC 60MG TABLET
02228	ADALAT CC 90MG TABLET
26587	ADCIRCA 20MG TABLET
35376	ADEMPAS 0.5MG TABLET
35383	ADEMPAS 1.5MG TABLET
35377	ADEMPAS 1MG TABLET
35385	ADEMPAS 2.5MG TABLET
35384	ADEMPAS 2MG TABLET
02682	AMLODIPINE 10MG TABLET
02681	AMLODIPINE 2.5MG TABLET
02683	AMLODIPINE 5MG TABLET
02363	CARDIZEM 120MG TABLET
02360	CARDIZEM 30MG TABLET
02361	CARDIZEM 60MG TABLET
02326	CARDIZEM CD 120MG CAPSULE
02323	CARDIZEM CD 180MG CAPSULE
02324	CARDIZEM CD 240MG CAPSULE
02325	CARDIZEM CD 300MG CAPSULE
07460	CARDIZEM CD 360MG CAPSULE
19183	CARDIZEM LA 180MG TABLET
02326	CARTIA XT 120MG CAPSULE

Step 3 (claim for alternate therapy)	
Required quantity: 1	
Look back timeframe: 730 days	
02323	CARTIA XT 180MG CAPSULE
02324	CARTIA XT 240MG CAPSULE
02325	CARTIA XT 300MG CAPSULE
07463	DILT XR 120MG CAPSULE
07461	DILT XR 180MG CAPSULE
07462	DILT XR 240MG CAPSULE
02363	DILTIAZEM 120MG CAPLET
02321	DILTIAZEM 120MG CAPSULE SA
02333	DILTIAZEM 300MG CAPSULE SA
02360	DILTIAZEM 30MG TABLET
02328	DILTIAZEM 360MG CAPSULE SA
02322	DILTIAZEM 60MG CAPSULE SA
02361	DILTIAZEM 60MG TABLET
02320	DILTIAZEM 90MG CAPSULE SA
02362	DILTIAZEM 90MG TABLET
02326	DILTIAZEM CD 120MG CAPSULE
02323	DILTIAZEM CD 180MG CAPSULE
02324	DILTIAZEM CD 240MG CAPSULE
02325	DILTIAZEM CD 300MG CAPSULE
07460	DILTIAZEM CD 360MG CAPSULE
02330	DILTIAZEM ER 120MG CAPSULE
07463	DILTIAZEM ER 120MG CAPSULE
02329	DILTIAZEM ER 180MG CAPSULE
07461	DILTIAZEM ER 180MG CAPSULE
02332	DILTIAZEM ER 240MG CAPSULE
07462	DILTIAZEM ER 240MG CAPSULE
94691	DILTIAZEM ER 420MG CAPSULE
02320	DILTIAZEM 12HR ER 90MG CAP
02622	FELODIPINE ER 10MG TABLET
02620	FELODIPINE ER 2.5MG TABLET
02621	FELODIPINE ER 5MG TABLET
02611	ISRADIPINE 2.5MG CAPSULE
02612	ISRADIPINE 5MG CAPSULE
98567	LETAIRIS 10MG TABLET
98566	LETAIRIS 5MG TABLET
19183	MATZIM LA 180MG TABLET
19184	MATZIM LA 240MG TABLET
19185	MATZIM LA 300MG TABLET

Step 3 (claim for alternate therapy)	
Required quantity: 1	
Look back timeframe: 730 days	
19186	MATZIM LA 360MG TABLET
19187	MATZIM LA 420MG TABLET
02390	NICARDIPINE 20MG CAPSULE
02391	NICARDIPINE 30MG CAPSULE
02226	NIFEDIPINE ER 30MG TABLET
02221	NIFEDIPINE ER 30MG TABLET
02222	NIFEDIPINE ER 60MG TABLET
02227	NIFEDIPINE ER 60MG TABLET
02228	NIFEDIPINE ER 90MG TABLET
02223	NIFEDIPINE ER 90MG TABLET
99446	NISOLDIPINE ER 17MG TABLET
99447	NISOLDIPINE ER 25.5MG TABLET
99448	NISOLDIPINE ER 34MG TABET
99445	NISOLDIPINE ER 8.5MG TABLET
02682	NORVASC 10MG TABLET
02681	NORVASC 2.5MG TABLET
02683	NORVASC 5MG TABLET
35443	OPSUMIT 10MG TABLET
35799	ORENITRAM ER 0.125MG TABLET
35798	ORENITRAM ER 0.25MG TABLET
35803	ORENITRAM ER 1MG TABLET
35804	ORENITRAM ER 2.5MG TABLET
02221	PROCARDIA XL 30MG TABLET
02222	PROCARDIA XL 60MG TABLET
02223	PROCARDIA XL 90 MG TABLET
33186	REVATIO 10MG/ML ORAL SUSP
24758	REVATIO 20MG TABLET
24758	SILDENAFIL 20MG TABLET
26587	TADALAFIL 20MG TABLET
02330	TAZTIA XT 120MG CAPSULE
02329	TAZTIA XT 180MG CAPSULE
02332	TAZTIA XT 240MG CAPSULE
02333	TAZTIA XT 300MG CAPSULE
02328	TAZTIA XT 360MG CAPSULE
14978	TRACLEER 125MG TABLET
43819	TRACLEER 32MG TABLET FOR SUSP
14979	TRACLEER 62.5MG TABLET
27492	TYVASO 1.74MG/2.9ML SOLUTION

Step 3 (claim for alternate therapy)	
Required quantity: 1	
Look back timeframe: 730 days	
27491	TYVASO INHALATION REFILL KIT
27489	TYVASO INHALATION STARTER KIT
40359	UPTRAVI 1,000MCG TABLET
40374	UPTRAVI 1,200MCG TABLET
40375	UPTRAVI 1,400MCG TABLET
40376	UPTRAVI 1,600MCG TABLET
40378	UPTRAVI 200-800 TITRATION PACK
40355	UPTRAVI 200MCG TABLET
40356	UPTRAVI 400MCG TABLET
40357	UPTRAVI 600MCG TABLET
40358	UPTRAVI 800MCG TABLET
26415	VENTAVIS 10MCG/1ML SOLUTION
21597	VENTAVIS 20MCG/1ML SOLUTION



Oral/Inhaled PH Agents

Drugs Requiring Clinical 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.

Label Name	GCN
ADEMPAS 0.5MG TABLET	35376
ADEMPAS 1 MG TABLET	35377
ADEMPAS 1.5MG TABLET	35383
ADEMPAS 2.5MG TABLET	35385
ADEMPAS 2MG TABLET	35384
AMBRISENTAN 10MG TABLET	98567
AMBRISENTAN 5MG TABLET	98566
BOSENTAN 125 MG TABLET	14978
BOSENTAN 62.5 MG TABLET	14979
LETAIRIS 10MG TABLET	98567
LETAIRIS 5MG TABLET	98566
OPSUMIT 10MG TABLET	35443
ORENITRAM ER 0.125MG TABLET	35799
ORENITRAM ER 0.25MG TABLET	35798
ORENITRAM ER 1MG TABLET	35803
ORENITRAM ER 2.5MG TABLET	35804
ORENITRAM ER 5MG TABLET	43521
TRACLEER 125MG TABLET	14978
TRACLEER 32MG TABLET FOR SUSP	43819
TRACLEER 62.5MG TABLET	14979
TYVASO 1.74MG/2.9ML SOLUTION	27492
TYVASO INHALATION REFILL KIT	27491
TYVASO INHALATION STARTER KIT	27489
UPTRAVI 1000MCG TABLET	40359
UPTRAVI 1200MCG TABLET	40374
UPTRAVI 1400MCG TABLET	40375
UPTRAVI 1600MCG TABLET	40376
UPTRAVI 200-800 TITRATION PACK	40378
UPTRAVI 200MCG TABLET	40355
UPTRAVI 400MCG TABLET	40356
UPTRAVI 600MCG TABLET	40357
UPTRAVI 800MCG TABLET	40358
VENTAVIS 10MCG/1ML SOLUTION	26415
VENTAVIS 20MCG/1ML SOLUTION	21597



Oral/Inhaled PH Agents

Clinical Criteria Logic

1. Does the client have a diagnosis of **pulmonary arterial hypertension (PAH)** in the last 730 days?
 - Yes, and the diagnosis is PAH – Go to #3
 - No, and the request is for riociguat – Go to #2
 - No, and the request is for a medication other than riociguat – Deny

2. Does the client have a diagnosis of **chronic thromboembolic pulmonary hypertension (CTEPH)** in the last 730 days?
 - Yes – Go to #4
 - No – Deny

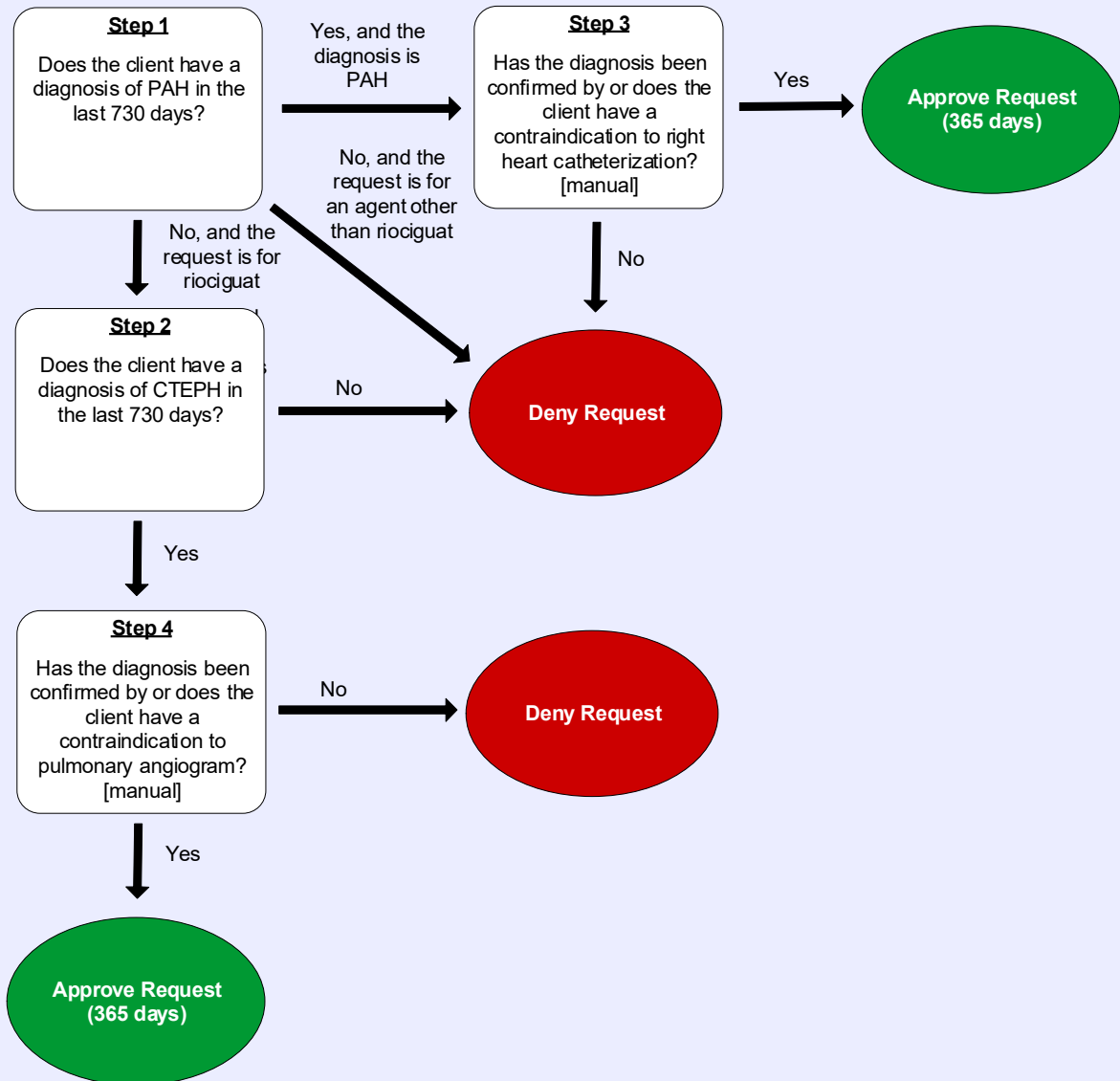
3. Has the diagnosis been confirmed by or does the client have a contraindication to right heart catheterization? [manual]
 - Yes – Approve (365 days)
 - No – Deny

4. Has the diagnosis been confirmed by or does the client have a contraindication to pulmonary angiogram? [manual]
 - Yes – Approve (365 days)
 - No – Deny



Oral/Inhaled PH Agents

Clinical Criteria Logic Diagram





Oral/Inhaled PH Agents

Clinical Criteria Supporting Tables

Step 1 (diagnosis of PAH) Required quantity: 1 Look back timeframe: 730 days	
ICD-10 Code	Description
I270	PRIMARY PULMONARY HYPERTENSION (PULMONARY ARTERIAL HYPERTENSION)

Step 2 (diagnosis of CTEPH) Required quantity: 1 Look back timeframe: 730 days	
ICD-10 Code	Description
I2724	CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION



Pulmonary Hypertension Agents

Clinical Criteria References

1. 2014 ICD-10-CM Diagnosis Codes, Volume 1. 2013. Available at <http://www.icd10data.com/>. Accessed on July 31, 2015.
2. McLaughlin VV, Archer SL, Badesch DB, et al. ACCF/AHA 2009 Expert Consensus Document on Pulmonary Hypertension: A Report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents and the American Heart Association: Developed in Collaboration with the American College of Chest Physicians, American Thoracic Society, Inc., and the Pulmonary Hypertension Association. *Circulation*. 2009;119:2250-2294.
3. Klinger JR, Elliott C, Levine DJ, et al. Therapy for Pulmonary Arterial Hypertension in Adults Update of the CHEST Guideline and Expert Panel Report. *Chest* 2019;155(3):565-586.
4. Humbert M, Kovacs G, Hoeper MM, et al. 2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension: Developed by the task force for the diagnosis and treatment of pulmonary hypertension of European Society of Cardiology (ESC) and European Respiratory Society (ERS). Endorsed by the International Society for Heart and Lung Transplantation (ISHLT) and the European Reference Network on rare respiratory diseases (ERN-LUNG). *European Heart Journal* (2022);43(38):3618-3731.
5. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2024. Available at www.clinicalpharmacology.com. Accessed on January 10, 2024.
6. Micromedex [online database]. Available at www.micromedexsolutions.com. Accessed on January 10, 2024.
7. Flolan Prescribing Information. Research Triangle Park, NC. GlaxoSmithKline. October 2023.
8. Remodulin Prescribing Information. Research Triangle Park, NC. United Therapeutics Corp. July 2021.
9. Veletri Prescribing Information. Titusville, NJ. Janssen Pharmaceuticals. July 2022.
10. Galie N, Corris PA, Frost A, et al. Updated Treatment Algorithm of Pulmonary Arterial Hypertension. *J Am Coll Cardiol*. 2013;62(25S).
11. Adempas Prescribing Information. Whippany, NJ. Bayer HealthCare Pharmaceuticals Inc. January 2023.

12. Letairis Prescribing Information. Foster City, CA. Gilead Sciences, Inc. August 2019.
13. Opsumit Prescribing Information. Titusville, NJ. Actelion Pharmaceuticals US, Inc. June 2023.
14. Orenitram Prescribing Information. Research Triangle Park, NC. United Therapeutics Corp. August 2023.
15. Tracleer Prescribing Information. Titusville, NJ. Janssen Pharmaceuticals. July 2022.
16. Tyvaso Prescribing Information. Research Triangle Park, NC. United Therapeutics Corp. May 2022.
17. Tyvaso DPI Prescribing Information. Research Triangle Park, NC. United Therapeutics Corp. June 2023.
18. Uptravi Prescribing Information. Titusville, NJ. Janssen Pharmaceuticals. July 2022.
19. Ventavis Prescribing Information. Titusville, NJ. Janssen Pharmaceuticals. March 2022.
20. Klinger JR, Elliott G, Levine DJ, et al. Updated Treatment Algorithm of Pulmonary Arterial Hypertension. *J Am Coll Cardiol*. 2013;62(25S).
21. Klinger JR, Elliott CG, Levine DL, et al. Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report. *Chest*. 2019;155(3):565-586.

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
08/21/2014	Presented to the DUR Board
11/24/2014	Initial publication and posting to website
07/31/2015	Review of ICD-9 and ICD-10 codes
08/01/2018	Annual review by staff Removed ICD-9 codes Updated Table 3 Updated references
10/11/2018	Updated to include GCN for Tracleer tablets for suspension
03/29/2019	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
07/15/2019	Annual review by staff Added GCNs for treprostinil to drug table Updated Table 3 Updated references
01/30/2020	Added criteria for Oral/Inhaled PH agents as approved by the DUR Board at the January 2020 DUR Board Meeting Updated references
02/13/2020	Updated drug table
10/07/2022	Annual review by staff Updated references
05/18/2023	Added GCNs for epoprostenol (33243, 30168) and Orenitam ER (43521) Updated references
01/10/2024	Annual review by staff Updated references