

Texas Prior Authorization Program Clinical Criteria

Drug/Drug Class

Androgenic Agents

Clinical Criteria Information Included in this Document

- **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

Added GCNs for Jatenzo (46152, 46153, 46144), testosterone gel (29905, 33452, 33453, 29647), and Tlando (52120) to PA table

Added Kyzatrex capsules to PA table (GCNs not yet available)

Removed GCNs for Androgel (47852), Axiron (29647), and Striant (19948) – these products have been discontinued

Added check for testosterone levels for initial and renewal requests

Removed question #2 (Is client male?) on logic and logic diagram



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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
ANDRODERM 2MG/24HR PATCH	30796
ANDRODERM 4MG/24HR PATCH	29171
ANDROGEL 1% (2.5G) GEL PACKET	47851
ANDROGEL 1% GEL PUMP	23141
ANDROGEL 1.62% (1.25G) GEL PACKET	33452
ANDROGEL 1.62% (2.5G) GEL PACKET	33453
ANDROGEL 1.62% GEL PUMP	29905
FORTESTA 10 MG GEL PUMP	98317
JATENZO 158 MG CAPSULE	46152
JATENZO 198 MG CAPSULE	46153
JATENZO 237 MG CAPSULE	46144
KYZATREX 100 MG CAPSULE	PENDING
KYZATREX 150 MG CAPSULE	PENDING
KYZATREX 200 MG CAPSULE	PENDING
NATESTO NASAL 5.5MG/0.122GM	38079
TESTIM 1% (50MG) GEL	97089
TESTOSTERONE 10MG GEL PUMP	98317
TESTOSTERONE 12.5MG/1.25GM	23141
TESTOSTERONE 1.62% GEL PUMP	29905
TESTOSTERONE 1.62% (1.25GM) PKT	33452
TESTOSTERONE 1.62% (2.5GM) PKT	33453
TESTOSTERONE 25MG/2.5GM	47851
TESTOSTERONE 30MG/1.5ML PUMP	29647
TESTOSTERONE 50MG/5GM GEL	97089
TESTOSTERONE 50MG/5GM PACKET	47852
TLANDO 112.5 MG CAPSULE	52120
VOGELXO 12.5MG/1.25GM PUMP	23141
VOGELXO 50MG/5GM GEL	97089
VOGELXO 50MG/5GM GEL PACKET	47852



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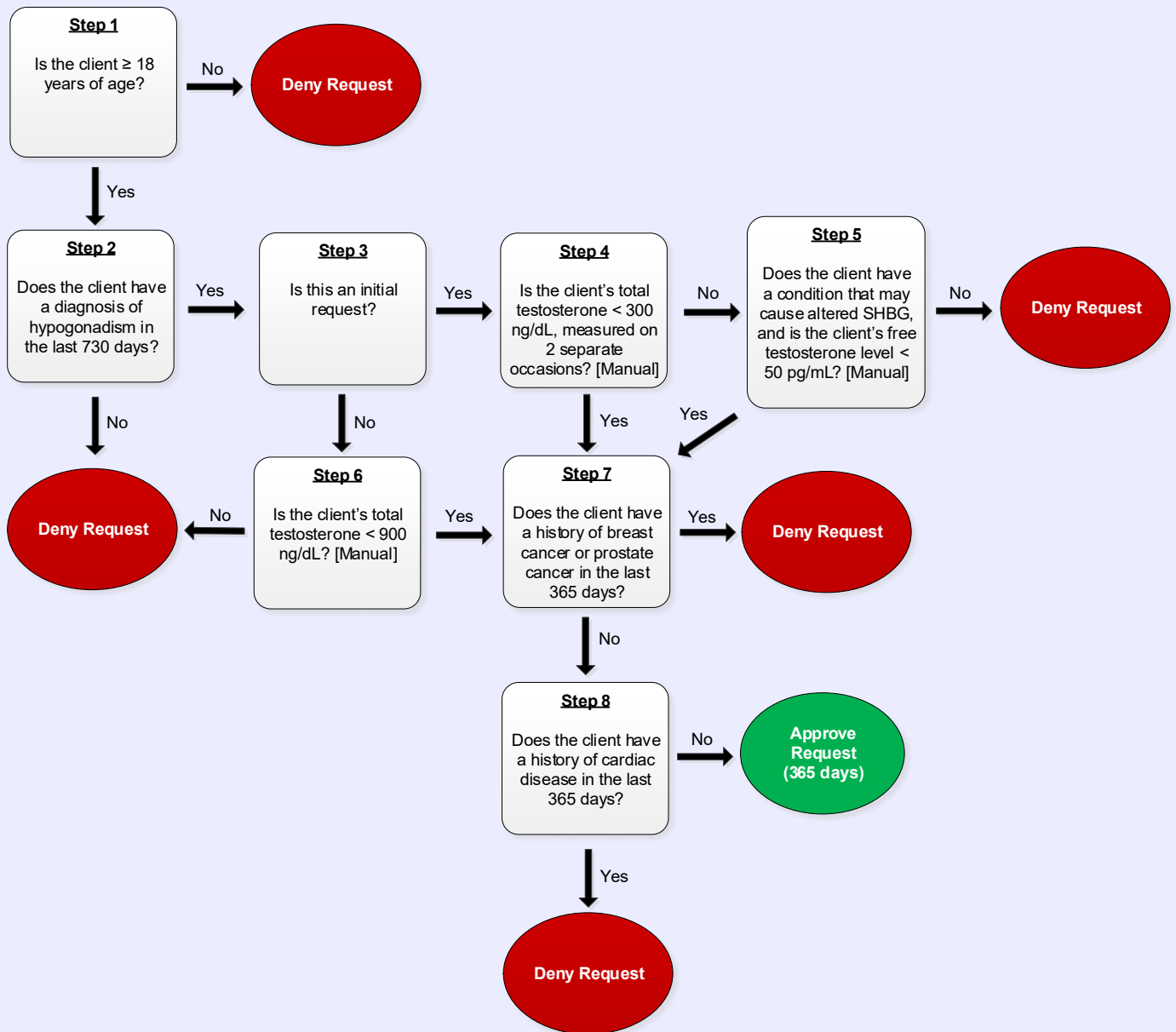
Clinical Criteria Logic

1. Is the client greater than or equal to (\geq) 18 years of age?
 Yes – Go to #2
 No – Deny
2. Does the client have a diagnosis of **hypogonadism** in the last 730 days?
 Yes – Go to #3
 No – Deny
3. Is this an initial request?
 Yes – Go to #4
 No – Go to #6
4. Is the client's initial total testosterone less than ($<$) 300 ng/dL, measured on 2 separate occasions? [Manual]
 Yes – Go to #7
 No – Go to #5
5. Does the client have a condition that may cause altered sex-hormone binding globulin (SHBG), and is the client's initial free or bioavailable testosterone level less than ($<$) 50 pg/mL? [Manual]
 Yes – Go to #7
 No – Deny
6. Is the client's current total testosterone less than or equal to (\leq) 900 ng/dL? [Manual]
 Yes – Go to #7
 No – Deny
7. Does the client have a history of **breast cancer or prostate cancer** in the last 365 days?
 Yes – Deny
 No – Go to #8
8. Does the client have a history of **cardiac disease** (including heart failure, coronary artery disease, and/or myocardial infarction) in the last 365 days?
 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 hypogonadism)	
Required quantity: 1	
Look back timeframe: 730 days	
ICD-10 Code	Description
E230	HYPOPITUITARISM
E291	TESTICULAR HYPOFUNCTION

Step 7 (history of breast or prostate cancer)	
Required quantity: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
C5002	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA, MALE
C50021	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA, RIGHT MALE BREAST
C50022	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA, LEFT MALE BREAST
C50029	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA, UNSPECIFIED MALE BREAST
C5012	MALIGNANT NEOPLASM OF CENTRAL PORTION OF BREAST, MALE
C50121	MALIGNANT NEOPLASM OF CENTRAL PORTION OF RIGHT MALE BREAST
C50122	MALIGNANT NEOPLASM OF CENTRAL PORTION OF LEFT MALE BREAST
C50129	MALIGNANT NEOPLASM OF CENTRAL PORTION OF UNSPECIFIED MALE BREAST
C5022	MALIGNANT NEOPLASM OF UPPER-INNER QUADRANT OF BREAST, MALE
C50221	MALIGNANT NEOPLASM OF UPPER-INNER QUADRANT OF RIGHT MALE BREAST
C50222	MALIGNANT NEOPLASM OF UPPER-INNER QUADRANT OF LEFT MALE BREAST
C50229	MALIGNANT NEOPLASM OF UPPER-INNER QUADRANT OF UNSPECIFIED MALE BREAST
C5032	MALIGNANT NEOPLASM OF LOWER-INNER QUADRANT OF BREAST, MALE
C50321	MALIGNANT NEOPLASM OF LOWER-INNER QUADRANT OF RIGHT MALE BREAST
C50322	MALIGNANT NEOPLASM OF LOWER-INNER QUADRANT OF LEFT MALE BREAST
C50329	MALIGNANT NEOPLASM OF LOWER-INNER QUADRANT OF UNSPECIFIED MALE BREAST

Step 7 (history of breast or prostate cancer)	
Required quantity: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
C5042	MALIGNANT NEOPLASM OF UPPER-OUTER QUADRANT OF BREAST, MALE
C50421	MALIGNANT NEOPLASM OF UPPER-OUTER QUADRANT OF RIGHT MALE BREAST
C50422	MALIGNANT NEOPLASM OF UPPER-OUTER QUADRANT OF LEFT MALE BREAST
C50429	MALIGNANT NEOPLASM OF UPPER-OUTER QUADRANT OF UNSPECIFIED MALE BREAST
C5052	MALIGNANT NEOPLASM OF LOWER-OUTER QUADRANT OF BREAST, MALE
C50521	MALIGNANT NEOPLASM OF LOWER-OUTER QUADRANT OF RIGHT MALE BREAST
C50522	MALIGNANT NEOPLASM OF LOWER-OUTER QUADRANT OF LEFT MALE BREAST
C50529	MALIGNANT NEOPLASM OF LOWER-OUTER QUADRANT OF UNSPECIFIED MALE BREAST
C5062	MALIGNANT NEOPLASM OF AXILLARY TAIL OF BREAST, MALE
C50621	MALIGNANT NEOPLASM OF AXILLARY TAIL OF RIGHT MALE BREAST
C50622	MALIGNANT NEOPLASM OF AXILLARY TAIL OF LEFT MALE BREAST
C50629	MALIGNANT NEOPLASM OF AXILLARY TAIL OF UNSPECIFIED MALE BREAST
C5082	MALIGNANT NEOPLASM OF OVERLAPPING SITES OF BREAST, MALE
C50821	MALIGNANT NEOPLASM OF OVERLAPPING SITES OF RIGHT MALE BREAST
C50822	MALIGNANT NEOPLASM OF OVERLAPPING SITES OF LEFT MALE BREAST
C50829	MALIGNANT NEOPLASM OF OVERLAPPING SITES OF UNSPECIFIED MALE BREAST
C5092	MALIGNANT NEOPLASM OF BREAST OF UNSPECIFIED SITE, MALE
C50921	MALIGNANT NEOPLASM OF BREAST OF UNSPECIFIED SITE OF RIGHT MALE BREAST
C50922	MALIGNANT NEOPLASM OF BREAST OF UNSPECIFIED SITE OF LEFT MALE BREAST
C50929	MALIGNANT NEOPLASM OF BREAST OF UNSPECIFIED SITE OF UNSPECIFIED MALE BREAST
C61	MALIGNANT NEOPLASM OF PROSTATE
C7981	SECONDARY MALIGNANT NEOPLASM OF BREAST

Step 8 (diagnosis of cardiac disease)	
Required quantity: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
I200	UNSTABLE ANGINA
I2101	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING LEFT MAIN CORONARY ARTERY
I2102	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING LEFT ANTERIOR DESCENDING CORONARY ARTERY
I2109	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING OTHER CORONARY ARTERY OF ANTERIOR WALL
I2111	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING RIGHT CORONARY ARTERY
I2119	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING OTHER CORONARY ARTERY OF INFERIOR WALL
I2121	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING LEFT CIRCUMFLEX CORONARY ARTERY
I2129	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING OTHER SITES
I213	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION OF UNSPECIFIED SITE
I214	NON-ST ELEVATION (NSTEMI) MYOCARDIAL INFARCTION
I220	SUBSEQUENT ST ELEVATION (STEMI) MYOCARDIAL INFARCTION OF ANTERIOR WALL
I221	SUBSEQUENT ST ELEVATION (STEMI) MYOCARDIAL INFARCTION OF INFERIOR WALL
I222	SUBSEQUENT NON-ST ELEVATION (NSTEMI) MYOCARDIAL INFARCTION
I228	SUBSEQUENT ST ELEVATION (STEMI) MYOCARDIAL INFARCTION OF OTHER SITES
I229	SUBSEQUENT ST ELEVATION (STEMI) MYOCARDIAL INFARCTION OF UNSPECIFIED SITE
I240	ACUTE CORONARY THROMBOSIS NOT RESULTING IN MYOCARDIAL INFARCTION
I241	DRESSLER'S SYNDROME
I248	OTHER FORMS OF ACUTE ISCHEMIC HEART DISEASE
I249	ACUTE ISCHEMIC HEART DISEASE, UNSPECIFIED
I2510	ATHEROSCLEROTIC HEART DISEASE OF NATIVE CORONARY ARTERY WITHOUT ANGINA PECTORIS
I25110	ATHEROSCLEROTIC HEART DISEASE OF NATIVE CORONARY ARTERY WITH UNSTABLE ANGINA PECTORIS
I25111	ATHEROSCLEROTIC HEART DISEASE OF NATIVE CORONARY ARTERY WITH UNSTABLE ANGINA PECTORIS WITH DOCUMENTED SPASM
I25118	ATHEROSCLEROTIC HEART DISEASE OF NATIVE CORONARY ARTERY WITH OTHER FORMS OF ANGINA PECTORIS
I25119	ATHEROSCLEROTIC HEART DISEASE OF NATIVE CORONARY ARTERY WITH UNSPECIFIED ANGINA PECTORIS

Step 8 (diagnosis of cardiac disease)	
Required quantity: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
I253	ANEURYSM OF HEART
I2541	CORONARY ARTERY ANEURYSM
I2542	CORONARY ARTERY DISSECTION
I255	ISCHEMIC CARDIOMYOPATHY
I256	SILENT MYOCARDIAL ISCHEMIA
I25700	ATHEROSCLEROSIS OF CORONARY ARTERY BYPASS GRAFT(S), UNSPECIFIED, WITH UNSTABLE ANGINA PECTORIS
I25701	ATHEROSCLEROSIS OF CORONARY ARTERY BYPASS GRAFT(S), UNSPECIFIED, WITH UNSTABLE ANGINA PECTORIS WITH DOCUMENTED SPASM
I25708	ATHEROSCLEROSIS OF CORONARY ARTERY BYPASS GRAFT(S), UNSPECIFIED, WITH OTHER FORMS OF ANGINA PECTORIS
I25709	ATHEROSCLEROSIS OF CORONARY ARTERY BYPASS GRAFT(S), UNSPECIFIED, WITH UNSPECIFIED ANGINA PECTORIS
I25710	ATHEROSCLEROSIS OF AUTOLOGOUS VEIN CORONARY ARTERY BYPASS GRAFT(S) WITH UNSTABLE ANGINA PECTORIS
I25711	ATHEROSCLEROSIS OF AUTOLOGOUS VEIN CORONARY ARTERY BYPASS GRAFT(S) WITH UNSTABLE ANGINA PECTORIS WITH DOCUMENTED SPASM
I25718	ATHEROSCLEROSIS OF AUTOLOGOUS VEIN CORONARY ARTERY BYPASS GRAFT(S) WITH OTHER FORMS OF ANGINA PECTORIS
I25719	ATHEROSCLEROSIS OF AUTOLOGOUS VEIN CORONARY ARTERY BYPASS GRAFT(S) WITH UNSPECIFIED ANGINA PECTORIS
I25720	ATHEROSCLEROSIS OF AUTOLOGOUS ARTERY CORONARY ARTERY BYPASS GRAFT(S) WITH UNSTABLE ANGINA PECTORIS
I25721	ATHEROSCLEROSIS OF AUTOLOGOUS ARTERY CORONARY ARTERY BYPASS GRAFT(S) WITH UNSTABLE ANGINA PECTORIS WITH DOCUMENTED SPASM
I25728	ATHEROSCLEROSIS OF AUTOLOGOUS ARTERY CORONARY ARTERY BYPASS GRAFT(S) WITH OTHER FORMS OF ANGINA PECTORIS
I25729	ATHEROSCLEROSIS OF AUTOLOGOUS ARTERY CORONARY ARTERY BYPASS GRAFT(S) WITH UNPECIFIED ANGINA PECTORIS
I25730	ATHEROSCLEROSIS OF NONAUTOLOGOUS BIOLOGICAL CORONARY ARTERY BYPASS GRAFT(S) WITH UNSTABLE ANGINA PECTORIS
I25731	ATHEROSCLEROSIS OF NONAUTOLOGOUS BIOLOGICAL CORONARY ARTERY BYPASS GRAFT(S) WITH UNSTABLE ANGINA PECTORIS WITH DOCUMENTED SPASM
I25738	ATHEROSCLEROSIS OF NONAUTOLOGOUS BIOLOGICAL CORONARY ARTERY BYPASS GRAFT(S) WITH OTHER FORMS OF ANGINA PECTORIS
I25739	ATHEROSCLEROSIS OF NONAUTOLOGOUS BIOLOGICAL CORONARY ARTERY BYPASS GRAFT(S) WITH UNSPECIFIED ANGINA PECTORIS

Step 8 (diagnosis of cardiac disease)	
Required quantity: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
I25750	ATHEROSCLEROSIS OF NATIVE CORONARY ARTERY OF TRANSPLANTED HEART WITH UNSTABLE ANGINA PECTORIS
I25751	ATHEROSCLEROSIS OF NATIVE CORONARY ARTERY OF TRANSPLANTED HEART WITH UNSTABLE ANGINA PECTORIS WITH DOCUMENTED SPASM
I25758	ATHEROSCLEROSIS OF NATIVE CORONARY ARTERY OF TRANSPLANTED HEART WITH OTHER FORMS OF ANGINA PECTORIS
I25759	ATHEROSCLEROSIS OF NATIVE CORONARY ARTERY OF TRANSPLANTED HEART WITH UNSPECIFIED ANGINA PECTORIS
I25760	ATHEROSCLEROSIS OF BYPASS GRAFT OF CORONARY ARTERY OF TRANSPLANTED HEART WITH UNSTABLE ANGINA PECTORIS
I25761	ATHEROSCLEROSIS OF BYPASS GRAFT OF CORONARY ARTERY OF TRANSPLANTED HEART WITH UNSTABLE ANGINA PECTORIS WITH DOCUMENTED SPASM
I25768	ATHEROSCLEROSIS OF BYPASS GRAFT OF CORONARY ARTERY OF TRANSPLANTED HEART WITH OTHER FORMS OF ANGINA PECTORIS
I25769	ATHEROSCLEROSIS OF BYPASS GRAFT OF CORONARY ARTERY OF TRANSPLANTED HEART WITH UNSPECIFIED ANGINA PECTORIS
I25790	ATHEROSCLEROSIS OF OTHER CORONARY ARTERY BYPASS GRAFT(S) WITH UNSTABLE ANGINA PECTORIS
I25791	ATHEROSCLEROSIS OF OTHER CORONARY ARTERY BYPASS GRAFT(S) WITH UNSTABLE ANGINA PECTORIS WITH DOCUMENTED SPASM
I25798	ATHEROSCLEROSIS OF OTHER CORONARY ARTERY BYPASS GRAFT(S) WITH OTHER FORMS OF ANGINA PECTORIS
I25799	ATHEROSCLEROSIS OF OTHER CORONARY ARTERY BYPASS GRAFT(S) WITH UNSPECIFIED ANGINA PECTORIS
I25810	ATHEROSCLEROSIS OF CORONARY ARTERY BYPASS GRAFT(S) WITHOUT ANGINA PECTORIS
I25811	ATHEROSCLEROSIS OF NATIVE CORONARY ARTERY OF TRANSPLANTED HEART WITHOUT ANGINA PECTORIS
I25812	ATHEROSCLEROSIS OF BYPASS GRAFT OF CORONARY ARTERY OF TRANSPLANTED HEART WITHOUT ANGINA PECTORIS
I2582	CHRONIC TOTAL OCCLUSION OF CORONARY ARTERY
I2583	CORONARY ATHEROSCLEROSIS DUE TO LIPID RICH PLAQUE
I2584	CORONARY ATHEROSCLEROSIS DUE TO CALCIFIED CORONARY LESION
I2589	OTHER FORMS OF CHRONIC ISCHEMIC HEART DISEASE
I259	CHRONIC ISCHEMIC HEART DISEASE, UNSPECIFIED
I501	LEFT VENTRICULAR FAILURE
I5020	UNSPECIFIED SYSTOLIC (CONGESTIVE) HEART FAILURE
I5021	ACUTE SYSTOLIC (CONGESTIVE) HEART FAILURE
I5022	CHRONIC SYSTOLIC (CONGESTIVE) HEART FAILURE

Step 8 (diagnosis of cardiac disease)	
Required quantity: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
I5023	ACUTE ON CHRONIC SYSTOLIC (CONGESTIVE) HEART FAILURE
I5030	UNSPECIFIED DIASTOLIC (CONGESTIVE) HEART FAILURE
I5031	ACUTE DIASTOLIC (CONGESTIVE) HEART FAILURE
I5032	CHRONIC DIASTOLIC (CONGESTIVE) HEART FAILURE
I5033	ACUTE ON CHRONIC DIASTOLIC (CONGESTIVE) HEART FAILURE
I5040	UNSPECIFIED COMBINED SYSTOLIC (CONGESTIVE) AND DIASTOLIC (CONGESTIVE) HEART FAILURE
I5041	ACUTE COMBINED SYSTOLIC (CONGESTIVE) AND DIASTOLIC (CONGESTIVE) HEART FAILURE
I5042	CHRONIC COMBINED SYSTOLIC (CONGESTIVE) AND DIASTOLIC (CONGESTIVE) HEART FAILURE
I5043	ACUTE ON CHRONIC COMBINED SYSTOLIC (CONGESTIVE) AND DIASTOLIC (CONGESTIVE) HEART FAILURE
I509	HEART FAILURE, UNSPECIFIED



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Clinical Criteria References

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9. Vogelxo Prescribing Information. Maple Grove, MN: Upsher-Smith Laboratories, Inc. April 2020.
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11. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone Therapy in Men With Hypogonadism: An Endocrine Society Clinical Practice Guideline. J Clin Endocr & Metab 2018;103(5):1715-1744. <https://academic.oup.com/jcem/article/103/5/1715/4939465?login=false>.
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13. Jatenzo Prescribing Information. Northbrook, IL: Clarus Therapeutics, Inc. March 2019.
14. Kyzatrex Prescribing information. Raleigh, NC: Marius Pharmaceuticals. July 2022.



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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
08/21/2014	Presented to the DUR Board
10/07/2014	Initial publication and posting to website
07/31/2015	Updated and revised ICD-9s and ICD-10s
02/01/2016	Added GCN for Natesto
05/08/2017	Annual review by staff References Updated
03/21/2019	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
10/22/2022	Added GCNs for Jatenzo (46152, 46153, 46144), testosterone gel (29905, 33452, 33453, 29647), and Tlando (52120) to PA table Added Kyzatrex to PA table; GCNs are not available yet Removed GCNs for Androgel (47852), Axiron (29647), and Striant (19948) – these products have been discontinued Added check for testosterone levels for initial and renewal requests
12/20/2022	Removed question #2 (Is client male?) on logic and logic diagram