

Topical, Nasal, and Oral Testosterone Products

Policy # 00335

Original Effective Date: 01/09/2013

Current Effective Date: 10/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on a review of the available data, branded AND generic topical, nasal, and oral testosterone products, including, but not limited to AndroGel[®]† (testosterone gel), Natesto[™]† (testosterone nasal gel), branded topical Testosterone, Vogelxo[®]† (testosterone gel), Jatenzo[®]† (testosterone undecanoate capsules), Tlando[®]† (testosterone undecanoate capsules), Kyzatrex[®]† (testosterone undecanoate capsules), Undecatrex[™]† (testosterone undecanoate capsules), Methitest[™]† (methyltestosterone) and Testim[®]† (testosterone gel) may be considered **eligible for coverage**** when the below patient selection criteria are met:

Patient Selection Criteria:

Coverage eligibility will be considered for branded or generic topical, nasal, and oral testosterone products when the following criteria are met for the requested drug:

- **For Jatenzo, Tlando, Kyzatrex, and Undecatrex requests:**
 - Patient is a male with hypogonadism (primary or secondary) as confirmed by serum testosterone measurements taken in the MORNING on TWO separate days BOTH showing levels BELOW the normal laboratory reference value; AND
 - Patient is 18 years of age or older; AND
 - Patient has tried and failed (e.g., intolerance or inadequate response) BOTH of the following prescription GENERIC products: testosterone enanthate vials for injection AND testosterone cypionate vials for injection unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)
 - Patient has tried and failed (e.g., intolerance or inadequate response) a generic topical testosterone product unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.
(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)

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- For **Methitest** requests:
 - Patient meets BOTH of the following:
 - Patient is a female who is 1 to 5 years postmenopausal; AND
 - Patient is using Methitest secondarily for advancing inoperable metastatic (skeletal) mammary cancer; OR
 - Patient is a premenopausal female with breast cancer who has benefitted from oophorectomy and is considered to have a hormone-responsive tumor; OR
 - The requested drug is being used for the treatment of delayed male puberty.
- For all other requests (topical and nasal):
 - Patient is a male with hypogonadism (primary or secondary) as confirmed by a low for age serum testosterone level defined by the normal laboratory reference value; AND
*(Note: The portion of this criterion regarding the testosterone level is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
 - For brand requests ONLY: There is clinical evidence or patient history that suggests the use of generic topical testosterone products will be ineffective or cause an adverse reaction to the patient.
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of branded or generic topical and nasal testosterone products in male patients when the patient does NOT have a low for age serum testosterone level (based on normal laboratory reference levels) when treating hypogonadism (primary or secondary) to be **not medically necessary.****

Based on review of available data, the Company considers the use of branded topical and nasal testosterone products, unless there is clinical evidence or patient history that suggests the use of generic topical testosterone products will be ineffective or cause an adverse reaction to the patient, to be **not medically necessary.****

Based on review of available data, the Company considers the use of Jatenzo (testosterone undecanoate capsules), Tlando (testosterone undecanoate capsules) Kyzatrex (testosterone undecanoate capsules), and Undecatrex (testosterone undecanoate capsules) when the patient has not tried and failed the prerequisite testosterone products to be **not medically necessary.****

Based on review of available data, the Company considers the use of Methitest (methyltestosterone) for the treatment of males with hypogonadism (primary or secondary) to be **not medically necessary.****

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of branded or generic topical, nasal, and oral testosterone products for 1.) indications such as athletic enhancement, 2.) contraindicated situations (e.g. male with carcinoma of the breast OR known or suspected carcinoma of the prostate (excluding males with treated and cured prostate cancer), or 3.) for usage not included in the above patient selection criteria to be **investigational**.*

Based on review of available data, the Company considers the use of Jatenzo (testosterone undecanoate capsules), Tlando (testosterone undecanoate capsules) Kyzatrex (testosterone undecanoate capsules), and Undecatrex (testosterone undecanoate capsules) when the patient selection criteria are not met (with the exception of those considered to be **not medically necessary****) to be **investigational**.*

Based on review of available data, the Company considers the use of Methitest (methyltestosterone) for the treatment of any other condition not listed above as **not medically necessary**** to be **investigational**.*

Policy Guidelines

Diagnosis of Androgen Deficiency

An established diagnosis of hypogonadism with androgen deficiency includes appropriate evaluation and diagnostic workup of a man who presents with symptoms of hypogonadism. Clinical practice guidelines recommend measuring serum testosterone only in men with consistent clinical manifestations of hypogonadism. Screening in asymptomatic populations is not recommended. Measurement of serum total testosterone is initially used; serum-free testosterone levels can be measured when total testosterone is in the low to normal range, and alterations of serum hormone binding globulin are suspected. Once a persistently low testosterone level has been established, diagnostic testing of the hypothalamic-pituitary axis should be performed to distinguish primary hypogonadism from secondary hypogonadism. When secondary hypogonadism is determined, the underlying etiology should be identified and any reversible causes treated appropriately before consideration of testosterone replacement.

Persistently low testosterone levels refer to serum levels below the lower limit of normal on at least 2 occasions when measured in the early morning (> 8:00 a.m.). The threshold lower limit for serum testosterone levels is not standardized. The Endocrine Society has recommended a lower limit for normal levels of 300 ng/dL for total testosterone and 9.0 ng/dL for free testosterone. Joint guidelines from several European and American specialty societies have recommended that replacement therapy be considered at serum total testosterone levels less than 350 ng/dL.

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Specific and suggestive symptoms of hypogonadism, as classified by the Endocrine Society, include the following:

- Incomplete or delayed sexual development
- Loss of axillar and/or pubic body hair
- Very small (< 6 mL) or shrinking testes
- Decreased libido
- Decreased spontaneous erections
- Breast discomfort, gynecomastia
- Eunuchoidal body proportions
- Infertility due to low sperm count
- Height loss due to vertebral fractures, low trauma fractures, low bone density
- Hot flushes, sweats.

Treatment of Hypogonadism with Testosterone

The Endocrine Society published clinical practice guidelines in 2018 on testosterone therapy in men with androgen deficiency. The summary of recommendations for testosterone therapy is as follows:

- We recommend testosterone therapy in hypogonadal men to induce and maintain secondary sex characteristics and correct symptoms of testosterone deficiency.
- We recommend against testosterone therapy in men planning fertility in the near term or in men with breast or prostate cancer, a palpable prostate nodule or induration, a prostate-specific antigen level > 4 ng/mL, a prostate-specific antigen level > 3 ng/mL combined with a high risk of prostate cancer (without further urological evaluation), elevated hematocrit, untreated severe obstructive sleep apnea, severe lower urinary tract symptoms, uncontrolled heart failure, myocardial infarction or stroke within the last 6 months, or thrombophilia.
- In hypogonadal men 55 to 69 years old, who are being considered for testosterone therapy and have a life expectancy > 10 years, we suggest discussing the potential benefits and risks of evaluating prostate cancer risk and prostate monitoring and engaging the patient in shared decision making regarding prostate cancer monitoring. For patients who choose monitoring, clinicians should assess prostate cancer risk before starting testosterone treatment and 3 to 12 months after starting testosterone. In hypogonadal men being considered for testosterone therapy who are 40 to 69 years old and at increased risk of prostate cancer (e.g., African Americans and men with a first-degree relative with diagnosed prostate cancer), we suggest discussing prostate cancer risk with the patient and offering monitoring options.
- We suggest against routinely prescribing testosterone therapy to all men 65 years or older with low testosterone concentrations. In men > 65 years who have symptoms or conditions suggestive of testosterone deficiency (such as low libido or unexplained anemia) and consistently and unequivocally low morning testosterone concentrations, we suggest that clinicians offer testosterone therapy on an individualized basis after explicit discussion of the potential risks and benefits.
- We suggest that clinicians consider short-term testosterone therapy in HIV-infected men with low testosterone concentrations and weight loss (when other causes of weight loss have been excluded) to induce and maintain body weight and lean mass gain.
- In men with type 2 diabetes mellitus who have low testosterone concentrations, we recommend against testosterone therapy as a means of improving glycemic control.

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Testosterone Dosage Guidelines

Dosing of testosterone varies depending on age, baseline testosterone levels, comorbid disease, response to initial replacement levels, and adverse reactions. General dosing guidelines are provided by the Endocrine Society. Specific dosing guidelines for the agents targeted by this medical policy, taken from the product prescribing information, follow:

- AndroGel: The starting dose of AndroGel is 50 mg of testosterone (two 25 mg packets or one 50 mg packet), applied once daily in the morning. The dose of AndroGel can be adjusted using 50 mg, 75 mg, or 100 mg of testosterone on the basis of total serum testosterone concentration. The dose should be titrated based on the serum testosterone concentration.
- Natesto: The recommended dose of Natesto is 11 mg of testosterone (2 pump actuations, one per nostril), applied intranasally three times daily.
- Vogelxo: The recommended starting dose of Vogelxo is 50 mg of testosterone (one tube, one packet, or 4 pump actuations) applied topically once daily at approximately the same time each day to clean, dry intact skin of the shoulders and/or upper arms. The maximum recommended dose of Vogelxo is 100 mg once daily.
- Jatenzo: The recommended starting dose of Jatenzo is 237 mg taken orally twice daily, once in the morning and once in the evening. The dose of Jatenzo should be adjusted based on serum testosterone measurements as presented in the prescribing information. The minimum recommended dose is 158 mg twice daily. The maximum recommended dose is 396 mg twice daily.
- Tlando: The recommended dosage of Tlando is 225 mg (taken as two 112.5 mg capsules), orally twice daily, once in the morning and once in the evening. Therapy with Tlando should only be continued if the serum testosterone is between 300-1080 ng/dL.
- Kyzatrex/Undecatrex: The recommended starting dose is 200 mg orally twice daily, once in the morning and once in the evening. The dose should be adjusted based on serum testosterone measurements as presented in the prescribing information. The minimum recommended dose is 100 mg once daily in the morning. The maximum recommended dose is 400 mg twice daily. For total daily doses greater than 100 mg, administer the same dose in the morning and evening.
- Testim: The recommended starting dose of Testim is 50 mg of testosterone (one tube) applied once daily (preferably in the morning) to clean, dry intact skin of the shoulder and/or upper arms. If the serum testosterone concentration is below the normal range (300 ng/dL to 1000 ng/dL), the daily Testim dose may be increased from 50 mg testosterone to 100 mg testosterone (two tubes) once daily. The maximum recommended dose of Testim is 100 mg once daily.

Monitoring Strategies for Individuals on Testosterone Therapy

Monitoring of testosterone replacement should be performed beginning 3 to 6 months after replacement is initiated to ascertain whether serum levels are restored to the normal range, to determine whether clinical symptoms have improved, and to monitor for adverse events. The goal of testosterone replacement is to raise levels into the mid-normal range (800 ng/dL or less). Higher replacement levels are unlikely to improve symptoms further and may increase the incidence and/or severity of adverse events.

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Recommendations for monitoring for testosterone-related adverse events have been provided by Endocrine Society guidelines on testosterone therapy in men with androgen deficiency. These recommendations include:

- Determine hematocrit levels at baseline, at 3 to 6 months, and then annually. If the hematocrit level is above 54%, stop therapy until the hematocrit level decreases to a safe level, evaluate the individual for hypoxia and sleep apnea, and reinstitute therapy at a reduced dose.
- Repeat bone mineral density of the lumbar spine, femoral neck, and hip after 1 to 2 years of testosterone therapy in hypogonadal men with osteoporosis.
- For men 55 to 69 years of age, and for men 40 to 69 years of age who are at increased risk for prostate cancer, conduct a digital examination of the prostate and prostate-specific antigen (PSA) measurement before initiating treatment, at 2 to 3 months after initiating treatment, and then in accordance with evidence-based guidelines for prostate cancer screening, depending on the age and race of the individual.
- Obtain urologic consultation if there is:
 - An increase in serum or plasma PSA concentration greater than 1.4 ng/mL within 12 months of initiating testosterone treatment.
 - A confirmed PSA of more than 4 ng/mL at any time.
 - Detection of a prostatic abnormality on digital rectal examination.
 - Substantial worsening of lower urinary tract symptoms.

Background/Overview

Transdermal, nasal, and buccal testosterone replacement products are indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. The prescribing information for these drugs defines those patients and/or conditions for which they are indicated:

- Primary hypogonadism (congenital or acquired) – testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter’s syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations accompanied by gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
- Secondary hypogonadism (i.e., hypogonadotropic hypogonadism) (congenital or acquired) – idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low serum testosterone concentrations without associated elevations in gonadotropins. Appropriate adrenal cortical and thyroid hormone replacement therapy may be necessary in patients with multiple pituitary or hypothalamic abnormalities.

Jatenzo, Tlando, Kyzatrex, and Undecatrex are oral testosterone replacement therapies used in adult males for conditions associated with a deficiency or absence of endogenous testosterone. The package inserts note that the prescriber should confirm the diagnosis of hypogonadism by ensuring that serum testosterone concentrations have been measured in the morning on at least two separate days and that these concentrations are below the normal range. Jatenzo, Tlando, Kyzatrex, and Undecatrex were not studied in comparison to the other testosterone formulations. All four medications were studied in an open label fashion.

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Methitest is an oral methyltestosterone product indicated for the treatment of conditions associated with a deficiency or absence of endogenous testosterone, such as primary or hypogonadotropic hypogonadism. It is also the only oral testosterone product FDA-approved for males with delayed puberty and for use in females for the palliative management of advanced inoperable metastatic breast cancer, though current clinical guidelines do not recommend it as a therapeutic option for either condition. The use of Methitest for testosterone replacement therapy is considered not medically necessary due to the availability of alternative testosterone formulations with more favorable safety profiles and clinical outcomes. Methitest has not been studied in direct comparison with other testosterone products.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Multiple topical testosterone products, a nasal testosterone product, and five oral testosterone products are U.S. Food and Drug Administration (FDA)-approved for the treatment of primary or secondary hypogonadism in males. Most of these products are contraindicated in women, excluding Methitest. They are also contraindicated in men with carcinoma of the breast or known or suspected carcinoma of the prostate (excluding males with treated and cured prostate cancer).

For topical and nasal testosterone products, the patient selection criteria presented in this policy take into consideration the FDA approved indications as well as clinical evidence or patient history that suggests generic topical testosterone products will be ineffective or cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above-mentioned caveats, there is no advantage of using branded topical or nasal testosterone products over generic topical testosterone products for testosterone replacement.

For Jatenzo, Tlando, Kyzatrex, and Undecatrex the patient selection criteria presented in this policy take into consideration the FDA approved indications as well as whether or not the patient has tried and failed other generic alternative formulations of testosterone. Based on a review of the data, in the absence of the above-mentioned caveats, there is no advantage of using Jatenzo, Tlando, Kyzatrex, or Undecatrex over generic topical and injectable testosterone products for testosterone replacement.

Clinical trial data supporting the safety and efficacy of Methitest is not included in the prescribing information.

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References

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10. Tlando [package insert]. Antares Pharma, Inc. March 2022.
11. Kyzatrex [package insert]. Raleigh, North Carolina. Marius Pharmaceuticals. July 2022.
12. Undecatrex [package insert]. San Antonio, Texas. Trifluent Pharma, LLC. September 2022.
13. Methitest [package insert]. Bridgewater, New Jersey. Amneal Pharmaceuticals. May 2025.

Policy History

Original Effective Date: 01/09/2013

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01/03/2013	Medical Policy Committee review
01/09/2013	Medical Policy Implementation Committee approval. New Policy
02/19/2013	Format revision. Coding section removed.
01/09/2014	Medical Policy Committee review
01/15/2014	Medical Policy Implementation Committee approval. No change to coverage.
10/02/2014	Medical Policy Committee review
10/15/2014	Medical Policy Implementation Committee approval. Added the statement that Axiron or Androgel should be used unless there is clinical evidence or patient history that suggests the use of Axiron or Androgel will be/was ineffective or will/did cause an adverse reaction to the patient.
10/08/2015	Medical Policy Committee review
10/21/2015	Medical Policy Implementation Committee approval. Added Nasal products to the policy. Title change.
10/06/2016	Medical Policy Committee review
10/19/2016	Medical Policy Implementation Committee approval. No change to coverage.
10/05/2017	Medical Policy Committee review
10/18/2017	Medical Policy Implementation Committee approval. Criteria changed to prefer Androgel 1.62% or generic products. Removed the indication of delayed puberty.
10/04/2018	Medical Policy Committee review
10/17/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/06/2018	Medical Policy Committee review

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12/19/2018	Medical Policy Implementation Committee approval. Removed the requirement to use Androgel 1.62% as this is now generic. Generic usage is still required. Updated language throughout to reflect this change.
12/05/2019	Medical Policy Committee review
12/11/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/03/2020	Medical Policy Committee review
12/09/2020	Medical Policy Implementation Committee approval. Title changed from “Topical and Nasal Testosterone Products” to “Topical, Nasal, and Oral Testosterone Products”. Added a new product, Jatenzo, to the policy. Updated relevant background information. Updated title to reflect the addition of an oral product to the policy.
12/02/2021	Medical Policy Committee review
12/08/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/02/2022	Medical Policy Committee review
06/08/2022	Medical Policy Implementation Committee approval. Added a new product, Tlando, to the medical policy and updated relevant sections.
02/02/2023	Medical Policy Committee review
02/08/2023	Medical Policy Implementation Committee approval. Added new drug, Kyzatrex, to the medical policy and updated relevant sections.
02/01/2024	Medical Policy Committee approval
02/14/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/06/2025	Medical Policy Committee review
02/12/2025	Medical Policy Implementation Committee approval. Added new drug, Undecatrex, to the medical policy and updated relevant sections. Removed discontinued products, Androderm, Axiron, Fortesta, and Striant, from medical policy.
10/02/2025	Medical Policy Committee review
10/08/2025	Medical Policy Implementation Committee approval. Added Methitest to policy with criteria. Updated relevant sections. Added policy guidelines section.
09/09/2026	Pre Pharmacy & Therapeutics Committee review.
09/16/2026	Pharmacy & Therapeutics Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 09/2027	

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

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- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan’s authorization for the same service under the same type of in-network benefit for a 90-day transition period.

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Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.