Select Erectile Dysfunction Medications

Policy # 00726
Original Effective Date: 01/01/2021
Current Effective Date: 01/01/2021

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.

Note: tadalafil 20 mg referenced in this policy is the generic equivalent for Cialis®. The generic equivalent of Adcirca® (tadalafil 20 mg, Alyq) is addressed separately in medical policy 00215 Advanced Therapies for Pharmacological Treatment of Pulmonary Hypertension.

Note: tadalafil 5 mg and Cialis® 5 mg are addressed separately in medical policy 00388 Cialis® 5 mg, generics (tadalafil).

Note: sildenafil 20 mg is addressed separately in medical policy 00215 Advanced Therapies for Pharmacological Treatment of Pulmonary Hypertension.

Note: This policy pertains to the pharmacy benefit ONLY.

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 review of available data, the Company may consider select erectile dysfunction medications (i.e., generic tadalafil 2.5 mg, 10 mg, and 20 mg tablets; generic sildenafil 25 mg, 50 mg, and 100 mg tablets; generic vardenafil film coated tablets; generic vardenafil orally disintegrating tablets [ODT]; brand Viagra®‡ [sildenafil] tablets; brand Levitra®‡ [vardenafil film coated] tablets; brand Staxyn®‡ [vardenafil orally disintegrating] tablets; brand Cialis®‡ [tadalafil] 2.5 mg, 10 mg, and 20 mg tablets; brand Stendra®‡ [avanafil] tablets; brand Caverject®‡/Impulse®‡ [alprostadil] injection; brand Muse®‡ [alprostadil] suppository; brand Edex®‡ [alprostadil] injection) in adults to be **eligible for coverage**** when the requested drug's patient selection criteria are met.

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Patient Selection Criteria

Coverage eligibility for the following erectile dysfunction medications in adults will be considered when the specific criteria are met for the requested drug:

- For generic tadalafil 2.5 mg, 10 mg, and 20 mg tablet requests OR generic sildenafil 25 mg, 50 mg, and 100 mg tablet requests:
    - Patient has a diagnosis of erectile dysfunction; OR
- For generic vardenafil film coated tablets/generic vardenafil ODT requests:
    - Patient has a diagnosis of erectile dysfunction; AND
    - Patient has tried and failed (e.g., intolerance or inadequate response) generic sildenafil (25 mg, 50 mg, or 100 mg) tablets AND generic tadalafil tablets 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; OR
      *(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)*
- For brand Viagra, Levitra, Staxyn, Cialis (2.5 mg, 10 mg, and 20 mg), and Stendra tablet requests:
    - Patient has a diagnosis of erectile dysfunction; AND
    - Patient has tried and failed (e.g., intolerance or inadequate response) the following 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:
        - For brand Viagra, Cialis (2.5 mg, 10 mg, and 20 mg), OR Stendra tablet requests:
            - Generic sildenafil 25 mg, 50 mg, or 100 mg tablets; AND
            - Generic tadalafil tablets; AND
            - Generic vardenafil tablets (film coated or ODT); OR
        - For brand Levitra tablet requests:
            - Generic sildenafil 25 mg, 50 mg, or 100 mg tablets; AND
            - Generic tadalafil tablets; AND
            - Generic vardenafil film coated tablets; OR
        - For brand Staxyn requests:
            - Generic sildenafil 25 mg, 50 mg, or 100 mg tablets; AND
            - Generic tadalafil tablets; AND
            - Generic vardenafil ODT tablets; OR

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*(Note: The above try and fail criteria are additional Company requirements for coverage eligibility and will be denied as not medically necessary** if not met)*

- For brand Caverject injection, Caverject Impulse injection, and Muse suppository requests:
  - Patient has a diagnosis of erectile dysfunction; OR
- For brand Edex injection requests:
  - Patient has a diagnosis of erectile dysfunction; AND
  - Erectile dysfunction is due to neurogenic, vasculogenic, psychogenic, or mixed etiology.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand Caverject/Caverject Impulse injection as a diagnostic test in the diagnosis of erectile dysfunction to be **not medically necessary**.**

Based on review of available data, the Company considers the use of erectile dysfunction medications listed in this policy when the specified prerequisite medications have not been tried and failed to be **not medically necessary**.**

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 generic sildenafil 20 mg tablets for the treatment of erectile dysfunction to be **investigational*.**

Based on review of available data, the Company considers the use of the erectile dysfunction medications listed in this policy for anything other than the treatment of erectile dysfunction (EXCEPT Caverject/Caverject Impulse injection as a diagnostic test, which is considered to be **not medically necessary****) to be **investigational*.**

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When Services Are Not Covered

Based on review of available data, The company considers the use of generic tadalafil 2.5 mg, 10 mg, and 20 mg tablets; generic sildenafil 25 mg, 50 mg, and 100 mg tablets; generic vardenafil film coated tablets; generic vardenafil ODT; brand Viagra tablets; brand Levitra tablets; brand Staxyn tablets; brand Cialis 2.5 mg, 10 mg, and 20 mg tablets; brand Stendra tablets; brand Caverject/Impulse injection; brand Muse suppository; or brand Edex injection in members under 18 years of age to be **not covered**.**

The company considers the use of the medications mentioned in this policy for members that exclude coverage for erectile dysfunction to be **not covered**.**

Note: The treatment of erectile dysfunction is considered an exclusion in most member contracts.

Background/Overview

The medications in the policy are used for the treatment of erectile dysfunction. Generic products in this class offer an economic advantage as compared to brand medications in this class.

Rationale/Source

The purpose of this medical policy is to ensure that these medications are being utilized appropriately and that the most economical, yet equally efficacious products are used prior to the more expensive products.

References

1. Cialis [package insert]. Eli Lilly. Indianapolis, Indiana. Updated June 2020.
2. Viagra [package insert]. Pfizer. New York, New York. Updated December 2017.
3. Levitra [package insert]. Glaxo Smith Kline. Research Triangle Park, North Carolina. Updated November 2018.
4. Stendra [package insert]. Metuchen Pharmaceuticals. Freehold, New Jersey. Updated September 2019.
5. Staxyn [package insert]. Glaxo Smith Kline. Research Triangle Park, North Carolina. Updated August 2017.
6. Caverject [package insert]. Pfizer. New York, New York. Updated December 2017.

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7. Muse [package insert]. Meda Pharmaceuticals. Somerset, New Jersey. Updated June 2017.
8. Edex [package insert]. Endo Pharmaceuticals, Inc. Malvern, Pennsylvania. Updated July 2018.

Policy History

Original Effective Date: 01/01/2021
Current Effective Date: 01/01/2021
12/03/2020 Medical Policy Committee review
12/09/2020 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 12/2021

*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
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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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:

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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.

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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.

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