Original Effective Date: 06/01/2019
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Last P&T Approval/Version: 01/29/2025
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Policy Number: C16658-A

Sexual Dysfunction Criteria NC

PRODUCTS AFFECTED

Addyi (flibanserin), Bi-Mix (papaverine/phentolamine), Caverject (alprostadil), Cialis (tadalafil) 10 mg, tadalafil 10 mg, Cialis (tadalafil) 20 mg, tadalafil 20 mg, Edex (alprostadil), Levitra (vardenafil), Muse (alprostadil), papaverine/phentolamine, Quad-Mix (papaverine/phentolamine/alprostadil/atropine), IFE-PG20 (alprostadil in NaCl), sildenafil, Staxyn (vardenafil), Stendra (avanafil), Super Bi-Mix, Super Quad-Mix, Super Tri-mix, Tri-Mix (papaverine/phentolamine/alprostadil), vardenafil, Viagra (sildenafil), Vyleesi (bremelanotide)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Sexual dysfunction

REQUIRED MEDICAL INFORMATION:
Medications used to treat sexual or erectile dysfunction are benefit exclusions as outlined in the Marketplace Evidence of Coverage.

Medications used to treat sexual or erectile dysfunction are excluded from coverage per Social Security 1927 (d)(3)(A).
A State may exclude or otherwise restrict coverage of a covered outpatient drug if the drug is contained in the list:

- Agents when used for anorexia, weight loss, or weight gain.
- Agents when used to promote fertility.
- Agents when used for cosmetic purposes or hair growth.
- Agents when used for the symptomatic relief of cough and colds.
- Agents when used to promote smoking cessation.

- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
- Nonprescription drugs, except, in the case of pregnant women when recommended in accordance with the Guideline referred to in section 1905(bb)(2)(A), agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.
- Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.
- Barbiturates.
- Benzodiazepines.
- **Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.**

CONTINUATION OF THERAPY:
NA

DURATION OF APPROVAL:
NA

PRESCRIBER REQUIREMENTS:
NA

AGE RESTRICTIONS:
NA

QUANTITY:
NA

PLACE OF ADMINISTRATION:
NA

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral, Urethral, Injectable

DRUG CLASS:
Impotence Agents, Hypoactive Sexual Desire Disorder (HSDD) Agents

FDA-APPROVED USES:
Indicated for the treatment of erectile dysfunction (ED), treatment of acquired, generalized hypoactive sexual desire disorder (HSDD) (also known as female sexual interest/arousal disorder)

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
State Specific Information
State Medicaid
New York (Source: New York State, Department of Health)

The Laws of New York Consolidated Laws of New York Chapter 55 Social Services Article 5 Title 11 Section 365-A "4. Any inconsistent provision of law notwithstanding, medical assistance shall not include, unless required by federal law and regulation as a condition of qualifying for federal financial participation in the medicaid program, the following items of care, services and supplies:…(e) drugs, procedures and supplies for the treatment of erectile dysfunction when provided to, or prescribed for use by, a person who is required to register as a sex offender pursuant to article six-C of the correction law,…(f) drugs for the treatment of sexual or erectile dysfunction, unless such drugs are used to treat a condition, other than sexual or erectile dysfunction, for which the drugs have been approved by the federal food and drug administration."
MUST check the Erectile Dysfunction Verification System (EDVS) for each request to determine member's sex offender status. IF a member is on the sex offender list the request must be forwarded to the medical director AND provider must provide the rationale for prescribing and note the reason(s) why alternative treatment options are inappropriate to treat the enrollee's health condition. Before issuing an adverse determination, the Medical Director must make reasonable attempts to engage in a peer–to–peer discussion with the requesting provider to understand the reasons behind the need for prescribing the requested drug. The Medical Director may extend the review time, if requested by the provider or patient, or if such extension is in the best interest of the patient's health condition.
For after-hours, holiday, and weekend pharmacy requests Molina Healthcare, Inc. can authorize a seventy-two (72) hour emergency supply of the requested product and must note within the authorization file that the drug is prescribed to treat a condition other than sexual or erectile dysfunction and that the drug has been approved by the FDA to treat that condition. The case must still be sent to the Medical director for checking the EDVS status of the member, as soon as possible on the next business day.
MOLINA REVIEWER NOTE: For any member on the sex offender list, approval can only be for 30 days per authorization.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
NA

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
NA

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Addyi TABS 100MG
Bi-Mix SOLR 150-5MG
Caverject Impulse KIT 10MCG, 20MCG
Caverject SOLR 20MCG, 40MCG
Cialis TABS 10MG, 20MG
Edex KIT 10MCG, 20MCG, 40MCG
Levitra TABS 10MG, 20MG
Muse PLLT 125MCG, 250MCG, 500MCG, 1000MCG
Quad-Mix SOLR 150-10-0.1-1MG
Sildenafil Citrate TABS 25MG, 50MG, 100MG
Staxyn TBDP 10MG
Stendra TABS 50MG, 100MG, 200MG
Super Bi-Mix SOLR 150-10MG
Super Quad-Mix SOLR 150-20-0.2-2MG
Super Tri-Mix SOLR 150-10-100MG-MG-MCG
Tadalafil TABS 10MG, 20MG
Tri-Mix SOLR 150-5-50MG-MG-MCG
Vardenafil HCl TABS 2.5MG, 5MG, 10MG, 20MG
Vardenafil HCl TBDP 10MG
Viagra TABS 25MG, 50MG, 100MG
Vyleesi SOAJ 1.75MG/0.3ML

REFERENCES

1. Addyi (flibanserin) [prescribing information], Raleigh, NC: Spout Pharmaceuticals, Inc., September 2021.
2. Caverject (alprostadil) [prescribing information], New York, NY: Pfizer Inc., March 2023.
3. Cialis (tadalafil) [prescribing information], Indianapolis, IN: Lily USA, LLC, June 2023.
4. Edex (alprostadil) [prescribing information], Malvern, PA: Endo Pharmaceuticals, Inc., March 2024.
5. Levitra (vardenafil) [prescribing information], Research Triangle Park, NC: GlaxoSmithKline, Inc., August 2017.
6. Viagra (sildenafil) [prescribing information], New York, NY: Pfizer Inc., December 2017.
7. Vyleesi (bremelanotide) [prescribing information], Cranbury, NJ: Palatin Technologies, Inc. March 2024.
8. Stendra (avanafil) tablet [prescribing information]. Freehold, NJ: Metuchen Pharmaceuticals, LLC; September 2019.
9. Staxyn (vardenafil) orally disintegrating tablets [prescribing information]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc.; March 2012.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information References	Q1 2025
REVISION- Notable revisions: Products Affected Available Dosage Forms References	Q1 2024
REVISION- Notable revisions: Products Affected Required Medical Information Drug Class Available Dosage Forms References	Q1 2023

REVISION- Notable revisions: Available Dosage Forms References	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file