



Original Effective Date: 06/01/2019
Current Effective Date: 02/25/2023
Last P&T Approval/Version: 01/25/2023
Next Review Due By: 01/2024
Policy Number: C16658-A

Sexual Dysfunction Criteria NC

PRODUCTS AFFECTED

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

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:

All uses of the products effected above are considered not medically necessary in accordance to this policy. Prescription drugs used to treat sexual or erectile dysfunction are NOT a covered benefit by Molina Healthcare.

This coverage policy is subject to change based on research and medical literature, or at the discretion of Molina Healthcare. Molina Healthcare will continue to evaluate and update this policy as relevant clinical evidence becomes available.

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:

NA

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

NA

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

NA

OTHER SPECIAL CONSIDERATIONS:

None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

Drug and Biologic Coverage Criteria

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

EDEX 20 MCG CARTRIDGE 2-PK& 6PK KIT	VIAGRA 25 MG TAB
EDEX 10 MCG CARTRIDGE 2-PK& 6PK KIT	VIAGRA 50 MG TAB
EDEX 40 MCG CARTRIDGE 2-PK& 6PK KIT	SILDENAFIL 50 MG TAB
MUSE 125 MCG, 250MCG, 500MCG, 1,000MCG URETHRAL SUPPOS	VIAGRA 100 MG TAB
CAVERJECT 20, 40 MCG VIAL	SILDENAFIL 100 MG TAB
CAVERJECT IMPULSE KIT 10, 20 MCG	TADALAFIL 10 MG TAB
IFE- PG20 100 MCG/5 ML VIAL	CIALIS 10 MG TAB
STENDRA 50 MG, 100MG, 200MG TABLET	TADALAFIL 20 MG TAB
ADDYI 100 MG TABLET	CIALIS 20 MG TAB
PPVRN 30MG-PHNT 1MG-ALPR 20MCG	VARDENAFIL HCL 2.5 MG TAB
PPVRN 12MG-PHNT 1MG-ALPR 10MCG	LEVITRA 2.5 MG TAB
PAPAVRN 30 MG-PHENTO 1MG/ML	VARDENAFIL HCL 5 MG TAB
BI-MIX 150-5 MG	LEVITRA 5 MG TAB
SUPER BI-MIX 150-10 MG	VARDENAFIL HCL 10 MG TAB
SILDENAFIL 25 MG TAB	VARDENAFIL HCL 10 MG TBDP
QUAD-MIX SOLR 150-10-0.1-1MG	LEVITRA 10 MG TAB
SUPER QUAD-MIX 150-20-0.2-2MG	VARDENAFIL HCL 20 MG TAB
TRI-MIX SOLR 150-5-50	LEVITRA 20 MG TAB
SUPER TRI-MIX SOLR 150-10-100	VARDENAFIL HCL 2.5 MG TAB
	STAXYN 10 MG ODT
	VARDENAFIL HCL 10 MG ODT
	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., December 2017
3. Cialis (tadalafil) [prescribing information], Indianapolis, IN: Lilly USA, LLC, February 2018
4. Edex (alprostadil) [prescribing information], Malvern, PA: Endo Pharmaceuticals, Inc., July 2018
5. Levitra (vardeafil) [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. February 2021
8. Stendra (avanafil) tablet [prescribing information]. Freehold, NJ: Metuchen Pharmaceuticals, LLC; September 2019.
9. Staxyn (vardeafil) orally disintegrating tablets [prescribing information]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc.; March 2012.

Drug and Biologic Coverage Criteria

SUMMARY OF REVIEW/REVISIONS	DATE
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