



AmeriHealth.

Policy Title Erectile Dysfunction Agents

Policy Number FS.CLIN.42

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification and age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy

Sildenafil (Viagra®), vardenafil (Levitra/Staxyn), tadalafil (Cialis®), and alprostadil (Muse®, Edex®, Caverject®) are indicated for the treatment of erectile dysfunction. Erectile dysfunction can be caused by any of the following:

- Neurogenic factors
- Spinal cord injury
- Vasculogenic factors
- Vascular disease
- Diabetes
- Psychogenic factors
- Psychological factors
- Mixed etiology
- Combination, defined as any of the three above-listed causes

Currently, two types of drugs are available to treat erectile dysfunction: alprostadil agents and selective inhibitors of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5).

The use of sildenafil (Viagra®), vardenafil (Levitra/Staxyn), tadalafil (Cialis®), and alprostadil (Muse®, Edex®, Caverject®) requires prior authorization (i.e., clinical pharmacy and/or Medical Director review).

Policy description

Sildenafil (Viagra®), vardenafil (Levitra/Staxyn), and tadalafil (Cialis®) inhibit an enzyme called phosphodiesterase-5 (PDE-5), which destroys cGMP. Cyclic guanosine monophosphate (cGMP) is a nucleotide that affects the amount of blood that is delivered to and removed from the penis. The longer cGMP persists, the longer the penis is engorged and able to maintain an erection. Thus, sildenafil (Viagra®), vardenafil (Levitra/Staxyn), and tadalafil (Cialis®) prevent the destruction of cGMP and allow it to accumulate and persist longer in vascular smooth muscle cells. Sildenafil (Viagra®), vardenafil (Levitra/Staxyn), and tadalafil (Cialis®) have no effect in the absence of sexual stimulation. Sildenafil (Viagra®), vardenafil (Levitra/Staxyn), and

tadalafil (Cialis®) should not be used in individuals who are currently taking nitrates due to risks related to hypotension.

Alprostadil (Muse®, Edex®, Caverject®) creates an erection by relaxing the smooth muscle tissue and dilating the major artery, thereby enhancing blood flow to the penis. These drugs are indicated for the treatment of all types of impotence.

Policy guideline inclusion

Erectile dysfunction agents are generally limited to a cumulative total of eight injections, tablets, or pellets per 30 days.

Exception: Cialis 2.5mg and Cialis 5mg are FDA-approved for once-daily dosing and are therefore limited to 30 units per 30 days.

FOR INDIVIDUALS 55 YEARS OF AGE AND OLDER:

Sildenafil (Viagra®), vardenafil (Levitra/Staxyn), and tadalafil (Cialis®) are approved when **BOTH** of the following inclusion criteria are met:

- Documentation of erectile dysfunction
- No documentation or history of nitrate use within the past six months

Alprostadil (Muse®, Edex®, Caverject®) is approved when the following inclusion criterion is met:

- Documentation of erectile dysfunction

FOR INDIVIDUALS YOUNGER THAN 55 YEARS OF AGE:

Sildenafil (Viagra®), vardenafil (Levitra/Staxyn), and tadalafil (Cialis®) are approved when **ALL** of the following inclusion criteria are met:

- Documentation of erectile dysfunction and **one** of the following:
 - Documentation of a concomitant condition (such as diabetes, prostate cancer, pelvic surgery, radiation [e.g. colon cancer], spinal cord injury, neurological disease)
 - Documentation of a normal testosterone level
 - Documentation of a low testosterone level and a low or normal prolactin level, with a trial and failure of/contraindication/intolerance/allergy to a testosterone-containing product
 - Documentation of a low testosterone level and a high prolactin level, with evidence of appropriate work up and treatment plan (treatment plan must be provided to the Company with this request)
- No documentation or history of nitrate use within the past six months

Alprostadil (Muse®, Edex®, Caverject®) is approved when the following inclusion criteria are met:

- Documentation of erectile dysfunction and **one** of the following:
 - Documentation of a concomitant condition (such as diabetes, prostate cancer, pelvic surgery, radiation [e.g. colon cancer], spinal cord injury, neurological disease)
 - Documentation of a normal testosterone level
 - Documentation of a low testosterone level and a low or normal prolactin level, with a trial and failure of/contraindication/intolerance/allergy to a testosterone-containing product
 - Documentation of a low testosterone level and a high prolactin level, with evidence of appropriate work up and treatment plan (treatment plan must be provided to the Company with this request)

Policy guideline exclusion

FOR INDIVIDUALS 55 YEARS OF AGE AND OLDER:

Sildenafil (Viagra®), vardenafil (Levitra/Staxyn), and tadalafil (Cialis®) are denied when **ANY** of the following exclusion criteria are present:

- No documentation of erectile dysfunction
- Documentation or history of nitrate use within the past six months

Alprostadil (Muse®, Edex®, Caverject®) is denied when the following exclusion criterion is present:

- No documentation of erectile dysfunction

FOR INDIVIDUALS YOUNGER THAN 55 YEARS OF AGE:

Sildenafil (Viagra®), vardenafil (Levitra/Staxyn), and tadalafil (Cialis®) are denied when **ANY** of the following inclusion criteria are met:

- No documentation of erectile dysfunction and **one** of the following:
 - No documentation of a concomitant condition (such as diabetes, prostate cancer, pelvic surgery, radiation [e.g., colon cancer], spinal cord injury, neurological disease)
 - No documentation of a normal testosterone level
 - No documentation of a low testosterone level and a low or normal prolactin level, with a trial and failure of/contraindication/intolerance/allergy to a testosterone-containing product
 - No documentation of a low testosterone level and a high prolactin level, with evidence of appropriate work up and treatment plan (treatment plan must be provided to the Company with this request)
- Documentation or history of nitrate use within the past six months

Alprostadil (Muse®, Edex®, Caverject®) is denied when the following exclusion criteria are present:

- No documentation of erectile dysfunction and **one** of the following:
 - No documentation of a concomitant condition (such as diabetes, prostate cancer, pelvic surgery, radiation [e.g., colon cancer], spinal cord injury, neurological disease)
 - No documentation of a normal testosterone level
 - No documentation of a low testosterone level and a low or normal prolactin level, with a trial and failure of/contraindication/intolerance/allergy to a testosterone-containing product
 - No documentation of a low testosterone level and a high prolactin level, with evidence of appropriate work up and treatment plan (treatment plan must be provided to the Company with this request)

Nitrates	
Brand Name	Generic Name
Amyl Nitrite Spirols	amyl nitrite
Amyl Nitrite Vaporole	amyl nitrite
Deponit	nitroglycerin
Dilatrate-SR	isosorbide dinitrate
Imdur	isosorbide mononitrate
ISDN	isosorbide dinitrate
ISMO	isosorbide mononitrate
Isochron	isosorbide dinitrate
Isordil	isosorbide dinitrate
Isordil Tembids	isosorbide dinitrate
Isordil Titradoso	isosorbide dinitrate
Isotrate-ER	isosorbide mononitrate
Minitran	nitroglycerin
Monoket	isosorbide mononitrate
Nitrek	nitroglycerin
Nitro-Bid	nitroglycerin
Nitrocine	nitroglycerin
Nitrocot	nitroglycerin
Nitrodisc	nitroglycerin
Nitro-Dur	Nitroglycerin

Nitrogard	Nitroglycerin
Nitroglyn	nitroglycerin
Nitrol	nitroglycerin
Nitrolingual	nitroglycerin
Nitrong	nitroglycerin
Nitro-Par	nitroglycerin
Nitroquick	nitroglycerin
Nitrostat	nitroglycerin
NitroTab	nitroglycerin
Nitro-Time	nitroglycerin
Sorbitrate	isosorbide dinitrate
Transderm-Nitro	nitroglycerin
Tridil	nitroglycerin

Policy List of Applicable Drugs

Erectile Dysfunction Agents	
Brand Name	Generic Name
Caverject	alprostadil
Cialis	tadalafil
Edex	alprostadil
Levitra	ardenafil
Muse	alprostadil
Staxyn	ardenafil
Viagra	sildenafil

Dosing and administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

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Policy link to related policies

Version effective date October 1, 2011

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