Drug Coverage Policy

Effective Date.....2/1/2025
Coverage Policy Number.....IP0100

Erectile Dysfunction – Avanafil

- Stendra™ (avanafil tablets - Mist Pharmaceuticals)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Medical Necessity Criteria

Coverage for brand Stendra varies across plans and may require the use of Step Therapy in accordance with benefit plan specifications. Refer to the customer's benefit plan document for coverage details.

For plans that do NOT include coverage for sexual dysfunction, medical necessity review may be required in addition to the Step Therapy requirements for non-sexual dysfunction uses. Refer to the customer's benefit plan document for coverage details.

Avanafil (Stendra) is considered medically necessary for the treatment of erectile dysfunction. However, erectile dysfunction therapy is specifically excluded under many benefit plans [both Employer Groups and Individual and Family Plans]. Please refer to the applicable benefit plan document to determine benefit availability and the terms and conditions of coverage (for example, quantity limitations).

Avanafil (Stendra) for Use as Needed for Erectile Dysfunction
Where covered, a maximum quantity limitation up to 8 tablets per 30 days is allowed.

When coverage requires the use of Step Therapy, coverage criteria are listed for products **in below table(s):**

Employer Plans:

Product	Criteria
Stendra (avanafil tablets)	**Stendra** is considered medically necessary when there is documentation of failure, contraindication, or intolerance to **TWO** of the following: 1. sildenafil 2. tadalafil 3. vardenafil

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Continuation of Avanafil (Stendra) is considered medically necessary when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven.

Background

OVERVIEW
Avanafil (Stendra, generic), a phosphodiesterase type 5 (PDE5) inhibitor, is indicated for the treatment of **erectile dysfunction**.[1]

References

1. Stendra™ tablets [prescribing information]. Cranford, NJ: Mist Pharmaceuticals; October 2022.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	• Updated coverage policy title.	5/1/2024

Annual Revision	**Policy Title: Updated from "**Erectile Dysfunction – Stendra" **to** "Erectile Dysfunction – Avanafil." The generic avanafil was added, where relevant, throughout the policy.	2/1/2025

The policy effective date is in force until updated or retired.