Reference number
1004-AMBST

Aetna Medicare Part B Drug Step Criteria

Botulinum Toxins

Preferred products:
Botox (onabotulinumtoxinA)
Xeomin (incobotulinumtoxinA)

This criteria document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization. Step criteria are applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Aetna Medicare Part B Drug Criteria. **Find Aetna Medicare Part B Drug Criteria documents**.

This program applies to botulinum toxins as specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude use of the preferred product and may be based on previous use of a product. The coverage review process will determine situations where a clinical exception can be made. This program applies to all Medicare members who are new to treatment with a targeted product.

For the indication(s) listed below (new starts only):

1. Blepharospasm
2. Cervical dystonia
3. Chronic sialorrhea
4. Upper limb spasticity

TABLE. Botulinum toxins

Status	Product(s)
Preferred*	Botox (onabotulinumtoxinA) – no prior authorization required Xeomin (incobotulinumtoxinA) – no prior authorization required
Non-preferred (targeted)**	Daxxify (daxibotulinumtoxinA-lanm) Dysport (abobotulinumtoxinA) Myobloc (rimabotulinumtoxinB)

*Preferred products do not require prior authorization

**Non-preferred products may not be indicated for all indications listed above

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5. All other requests

TABLE. Botulinum toxins

Status	Product(s)
Preferred*	Botox (onabotulinumtoxinA) – no prior authorization required
Non-preferred (targeted)	Daxxify (daxibotulinumtoxinA-lanm) Dysport (abobotulinumtoxinA) Myobloc (rimabotulinumtoxinB)

*Preferred product does not require prior authorization

EXCEPTION CRITERIA

Coverage for the targeted product(s) is provided when the member meets one or more of the following criteria:

1. Member has received an authorized dose of the requested product in the past 365 days (does not include samples or doses administered without prior authorization)
2. Documented inadequate response to a trial of one or more of the preferred products (documentation required upon request)
3. Documented intolerable adverse event to one or more of the preferred products (documentation required upon request)
4. The preferred products are contraindicated for the member

REFERENCES

1. Botox (onabotulinumtoxinA) [package insert]. Madison, NJ: Allergan USA, Inc.; August 2022.
2. Daxxify (daxibotulinumtoxinA-lanm) [package insert]. Newark, CA: Revance Therapeutics, Inc.; August 2023.
3. Myobloc (rimabotulinumtoxinB) [package insert]. Louisville, KY: Solstice Neurosciences, Inc.; March 2021.
4. Dysport (abobotulinumtoxinA) [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; July 2020.
5. Xeomin (incobotulinumtoxinA) [package insert]. Raleigh, NC: Merz Pharmaceuticals, LLC.; August 2021.
6. Micromedex [database online]. New York, NY: Thomson Reuters, Inc.; 2019. Available at http://www.micromedexsolutions.com/micromedex2/librarian. Updated periodically. Accessed February 2020.
7. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at http://www.clinicalpharmacology-ip.com/default.aspx. Updated periodically. Accessed February 2020.

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See Evidence of Coverage for a complete description of plan benefits, exclusions, limitations and conditions of coverage. Plan features and availability may vary by service area.
The formulary may change at any time. You will receive notice when necessary.

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