Abobotulinumtoxin A (Dysport®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- Treatment of cervical dystonia in adults
- Treatment of spasticity in patients 2 years of age and older

Compendial Uses

- Blepharospasm
- Hemifacial spasm
- Chronic anal fissures
- Excessive salivation
- Primary axillary hyperhidrosis

All other indications are considered experimental/investigational and not medically necessary.

EXCLUSIONS

Coverage will not be provided for cosmetic use.

COVERAGE CRITERIA

Cervical Dystonia

Authorization of 12 months may be granted for treatment of adults with cervical dystonia (e.g., torticollis) when all of the following are met:

- Member is 18 years of age or older
- Member has abnormal placement of the head with limited range of motion in the neck.

Upper or Lower Limb Spasticity

Authorization of 12 months may be granted for treatment of upper or lower limb spasticity when all of the following are met:

- Member is 2 years of age or older
- Member has a primary diagnosis of upper or lower limb spasticity or as a symptom of a condition (including focal spasticity or equinus gait due to cerebral palsy)

Blepharospasm

Authorization of 12 months may be granted for treatment of blepharospasm, including blepharospasm associated with dystonia and benign essential blepharospasm.

Hemifacial Spasm

Authorization of 12 months may be granted for treatment of hemifacial spasm.

Chronic Anal Fissures

Authorization of 12 months may be granted for treatment of chronic anal fissures when the member has not responded to first-line therapy such as topical calcium channel blockers or topical nitrates.

Excessive Salivation

Authorization of 12 months may be granted for treatment of excessive salivation (chronic sialorrhea) when the member has been refractory to pharmacotherapy (e.g., anticholinergics).

Primary Axillary Hyperhidrosis

Authorization of 12 months may be granted for treatment of primary axillary hyperhidrosis when all of the following criteria are met:

- Significant disruption of professional and/or social life has occurred because of excessive sweating; and
- Topical aluminum chloride or other extra-strength antiperspirants are ineffective or result in a severe rash.

CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria and be experiencing benefit from therapy.

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Dysport (AbobotulinumtoxinA)	Blepharospasm	Route of Administration: Subcutaneous 120Units per affected eye. May repeat no sooner than every 12 weeks
Dysport (AbobotulinumtoxinA)	Cervical Dystonia	Route of Administration: Intramuscular ≥18 year(s) 1000Units divided among the affected muscles. May re-treat no sooner than every 12 weeks.
Dysport (AbobotulinumtoxinA)	Chronic Anal Fissures	Route of Administration: Intramuscular 150Units per treatment. May re-treat no sooner than every 12 weeks.

Dysport (AbobotulinumtoxinA)	Excessive Salivation (Chronic Sialorrhea or Ptyalism)	Route of Administration: Injection 450Units per treatment. May re-treat no sooner than every 12 weeks.
Dysport (AbobotulinumtoxinA)	Hemifacial Spasm	Route of Administration: Subcutaneous 220Units per treatment. May re-treat no sooner than every 12 weeks.
Dysport (AbobotulinumtoxinA)	Primary Axillary Hyperhidrosis	Route of Administration: Intradermal 200 Units per axilla. May re-treat no sooner than every 12 weeks.
Dysport (AbobotulinumtoxinA)	Upper or Lower Limb Spasticity	Route of Administration: Intramuscular ≥2 to <18 year(s) <33.33 kg 30Units/kg total for upper and lower limb combined per treatment (up to 16 units/kg per upper limb and up to 15 units/kg per lower limb). May re-treat no sooner than every 12 weeks. ≥33.34 kg 1000Units total for upper and lower limb combined per treatment (up to 16 units/kg or 640 units, whichever is lower, for upper limb; up to 15 units/kg unilateral or 1000 units, whichever is lower, for lower limb). May re-treat no sooner than every 12 weeks. ~~1000Units per treatment. May re-treat no sooner than every 12 weeks.~~ ≥18 year(s) 1500Units total for upper and lower limb combined per treatment (up to 1000 units for upper limb and up to 1500 units for lower limb). May re-treat no sooner than every 12 weeks.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

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6. Lakraj AA, Moghimi N, Jabbari B. Sialorrhea: Anatomy, Pathophysiology and Treatment with Emphasis on the Role of Botulinum Toxins. Toxins 2013, 5, 1010-1031
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EFFECTIVE DATE

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