DRUG DETERMINATION POLICY

Title: DDP-42 Hyperhidrosis Agents

Effective Date: 06/27/2022

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

Botox and Qbrexza are agents used to treat hyperhidrosis and are associated with significant toxicity. These criteria were developed and implemented to ensure appropriate use for the intended diagnoses and mitigation of toxicity, if possible.

3.0 Clinical Determination Guidelines:

Document the following with chart notes:

I. Botox (onabotulinumtoxinA).

A. Age: at least 18 years.

B. Diagnosis and severity [must meet all listed below]:

1. Severe primary axillary hyperhidrosis not adequately managed by topical agents.

2. Hyperhidrosis Disease Severity Scale: 3 or 4 (see Appendix I).

3. The condition is causing persistent or chronic cutaneous conditions (e.g., skin maceration, dermatitis, fungal infection, secondary microbial infections).

C. Other therapies: contraindicated, inadequate response or significant adverse effects to two topical therapies for two months each; one being 20% aluminum chloride hexahydrate.

D. Dosage regimen: 50 units per axilla every six months.

E. Approval:

1. Initial: one year or two doses.

2. Re-approval: at least one year or three doses; must document reduction in Hyperhidrosis Disease Severity Score.

II. Qbrexza (glycopyrronium cloth)

A. Age: at least nine years.

B. Diagnosis and severity [must meet all listed below]:

1. Severe primary axillary hyperhidrosis not adequately managed by topical agents.

2. Hyperhidrosis Disease Severity Scale: 3 or 4 (see Appendix I).

3. The condition is causing persistent or chronic cutaneous conditions (e.g., skin maceration, dermatitis, fungal infection, secondary microbial infections).

C. Other therapies: contraindicated, inadequate response or significant adverse effects to therapies dependent on age [must meet one listed below]:

1. Member age under 18 years:

a. Topical therapies: two topical therapies for two months each, one being 20% aluminum chloride hexahydrate.

2. Member age at least 18 years [must meet both listed below]:

a. Botulinum toxin: six-month trial or two doses (not indicated under 18 years old).

b. Topical therapies: two topical therapies for two months each, one being 20% aluminum chloride hexahydrate.

D. Dosage regimen: apply one pad to each underarm once daily.

E. Approval:

1. Initial: six months.

2. Re-approval: one year; must document reduction in Hyperhidrosis Disease Severity Score.

4.0 Coding:

AFFECTED CODES				
Code	**Brand Name**	**Generic Name**	**Billing Units (1U)**	**Prior Approval**
J0585	Botox	onabotulinumtoxinA	1	Y
N/A	Qbrexza	glycopyrronium cloth	N/A	Y

5.0 References, Citations & Resources:

1. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Onbotulinumtoxina injection, Qbrexza accessed May 2021.
2. UpToDate: Primary focal hyperhidrosis: https://www.uptodate.com/contents/primary-focal-hyperhidrosis?search=hyperhidrosis%20treatment&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1, accessed May 2021.

6.0 Appendices:

See page 4.

7.0 Revision History:

Original Effective Date: 06/27/2022

Next Review Date: 06/27/2022

Revision Date	Reason for Revision
4/20	Annual review; other therapies verbiage, formating; approved at June P&T Committee meeting.
5/21	Annual review; clarified criteria instructions, reformated
04/27/2022	Annual review ready for May P and T workgroups and the June P and T committee meeting

Appendix I: Hyperhidrosis Disease Severity Scale (HDSS)

Scale	**Underarm Sweating Severity**
1	Never noticeable/never interfers with my daily activities
2	Tolerable/sometimes interfers with my daily activities
3	Barely tolerable/frequently interfers with my daily activities
4	Intolerable/always interfering with my daily activities

Appendix II Monitoring and Patient Safety

Drug	Adverse Reactions*	Monitoring	REMS
Botox Onabotulinmum Toxin	• Cervical Dystonia: dysphagia (19%), upper respiratory infections (12%), headache/neck pain (11%) • Blepharospasm: ptosis (21%), eye dryness, superficial punctate keratitis (6%) • Chronic Migraine: muscular weakness (4%), neck pain (9%) • Urinary Incontinence: urinary retention (17%), urinary track infection (24%) • Upper Limb Spasticity: pain in extremity (6-9%) • Strabismus: ptosis (16-38%) • Black Box: dysphagia, breathing difficulties • Pregnancy Category C	• Monitor those with motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junction disease (myasthenia gravis, Lambert-Eaton Syndrome)	• No longer required
Qbrexza glycopyrronium	• Dermatological: erythema (17%), burning/stinging sensation of skin (14%) • Gastrointestinal: xerostomia (24%)	• Anticholinergic effects	• None needed

**Adverse drug reaction for Botox based on diagnosis being treated*