

**Sofdra (sofpironium)**  
**Effective 03/01/2025**

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange		Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit			<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A			
Contact Information	Medical Benefit Pharmacy Benefit	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029	
Exceptions	N/A			

**Overview**

Sofdra (sofpironium) is an anticholinergic indicated for the treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older.

**Coverage Guidelines**

Authorization may be granted for members new to the plan within the last 90 days who are currently receiving treatment with the requested medication and are stable, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

**OR**

Authorization may be granted when all of the following criteria are met:

1. Diagnosis of primary axillary hyperhidrosis
2. Provider attestation that other causes of hyperhidrosis (e.g., menopause, medications) have been ruled out
3. Member is 9 years of age or older
4. Member has had an inadequate response, adverse reaction, or contraindication to an aluminum-containing anti-perspirant (e.g., Drysol)

**Continuation of Therapy**

Requests for reauthorization will be approved when the following criteria are met:

1. Member has had a positive clinical response to therapy

**Limitations**

1. Initial and reauthorization requests will be approved for 12 months
2. The following quantity limitations apply:

Drug Name	Quantity Limit
Sofdra	1 bottle (40.2 mL) per 30 days

**References**

1. Glaser DA, Hebert AA, Nast A, et al. A 44-week open-label study evaluating safety and efficacy of topical glycopyrronium tosylate in patients with primary axillary hyperhidrosis. *Am J Clin Dermatol*. 2019[a];20(4):593-604. doi: 10.1007/s40257-019-00446-6.

2. Glaser DA, Hebert AA, Nast A, et al. Topical glycopyrronium tosylate for the treatment of primary axillary hyperhidrosis: Results from the ATMOS-1 and ATMOS-2 phase 3 randomized controlled trials. *J Am Acad Dermatol*. 2019[b];80(1):128-138.e2. doi: 10.1016/j.jaad.2018.07.002.
3. International Hyperhidrosis Society. Primary axillary hyperhidrosis treatment algorithm. Updated September 23, 2018. Accessed August 8, 2024. <https://www.sweathelp.org/treatments-hcp/clinical-guidelines/primary-focal-hyperhidrosis/primary-focal-axillary.html>
4. Kisielnicka A, Szczerkowska-Dobosz A, Purzycka-Bohdan D, Nowicki RJ. Hyperhidrosis: disease aetiology, classification and management in the light of modern treatment modalities. *Postepy Dermatol Alergol*. 2022;39(2):251-257. doi: 10.5114/ada.2022.115887.
5. Scholes KT, Crow KD, Ellis JP, Harman RR, Saihan EM. Axillary hyperhidrosis treated with alcoholic solution of aluminum chloride hexahydrate. *Br Med J*. 1978;2:84-85.
6. Sofdra (sofpironium) [prescribing information]. Botanix SB Inc: Wayne, PA; June 2024.
7. Stuart ME, Strite SA, Gillard KK. A systematic evidence-based review of treatments for primary hyperhidrosis. *J Drug Assess*. 2020;10(1):35-50. doi: 10.1080/21556660.2020.1857149.
8. Vorkamp T, Foo FJ, Khan S, Schmitto JD, Wilson P. Hyperhidrosis: evolving concepts and a comprehensive review. *Surgeon*. 2010;8(5):287-292.
9. Wade R, Rice S, Llewellyn A, et al. Interventions for hyperhidrosis in secondary care: a systematic review and value-of-information analysis. *Health Technol Assess*. 2017;21(80):1-280.

#### Review History

12/11/2024 – Created and reviewed at December P&T. Effective 03/01/2025.

