

Louisiana Medicaid Hereditary Angioedema

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for medications used to treat or prevent hereditary angioedema (HAE).

Additional Point-of-Sale edits may apply.

By submitting the authorization request, the prescriber attests to the conditions available [HERE](#).

HAE Medication Use and Minimum Age per Current Drug-Specific Prescribing Information			
Medication	Brand	Use	Minimum Age
Berotralstat	Orladeyo®	Prophylaxis	≥2
C1 Esterase Inhibitor (Human)	Berinert®	Treatment	5
C1 Esterase Inhibitor (Human)	Cinryze®	Prophylaxis	6
C1 Esterase Inhibitor Subcutaneous (Human)	Haegarda®	Prophylaxis	6
C1 Esterase Inhibitor (Recombinant)	Ruconest®	Treatment	13
Donidalorsen	Dawnzera™	Prophylaxis	12
Ecallantide	Kalbitor®	Treatment	12
Icatibant	Firazyr®	Treatment	18
Lanadelumab-flyo	Takhzyro™	Prophylaxis	2
Sebetralstat	Ekterly®	Treatment	12

Approval Criteria for Initiation of Therapy

- The recipient has a diagnosis of HAE; **AND**
- The recipient's age on the date of the request is not less than the minimum age recommended in the prescribing information (see table); **AND**
- The requested medication is used as recommended in the prescribing information for either prevention or treatment (see table); **AND**
- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc. **AND**
- **ONE** of the following is true and **stated on the request**:
 - If the requested medication is used for HAE prophylaxis, the requested medication is not prescribed concurrently with another medication for HAE prophylaxis; **OR**
 - If the requested medication is used for the treatment of HAE, the requested medication is not prescribed concurrently with another medication for the treatment HAE; **AND**
- If the request is for a non-preferred agent - **ONE** of the following is required:
 - The recipient has had a *treatment failure* with at least one preferred drug that is appropriate to use for the condition being treated; **OR**
 - The recipient has had an *intolerable side effect* to at least one preferred drug that is appropriate to use for the condition being treated; **OR**
 - The recipient has *documented contraindication(s)* to the preferred drugs that are appropriate to use for the condition being treated; **OR**
 - There is *no preferred product that is appropriate* to use for the condition

being treated.

Approval Criteria for Continuation of Therapy

- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy; **AND**
- **ONE** of the following is true and **stated on the request**:
 - If the requested medication is used for HAE prophylaxis, the requested medication is not prescribed concurrently with another medication for HAE prophylaxis; **OR**
 - If the requested medication is used for the treatment of HAE, the requested medication is not prescribed concurrently with another medication for the treatment HAE.

Duration of approval for initiation and continuation of therapy: 12 months

References

Berinert (C1 Esterase Inhibitor – Human) [package insert]. Kankakee, IL: CSL Behring LLC; September 2021. <http://labeling.cslbehring.com/PI/US/Berinert/EN/Berinert-Prescribing-Information.pdf>

Cinryze (C1 Esterase Inhibitor – Human) [package insert]. Lexington, MA: Shire ViroPharma Incorporated; February 2023. http://pi.shirecontent.com/PI/PDFs/Cinryze_USA_ENG.pdf

Dawnzera (donidalorsen) [package insert]. Carlsbad, CA: Ionis Pharmaceuticals, Inc; August 2025. <https://ionis.com/medicines/DAWNZERA/DAWNZERA-FPI.pdf>

Ekterly (sebetralstat) [package insert]. Cambridge, MA: KalVista Pharmaceuticals, Inc; July 2025. <https://www.kalvista.com/ekterly-us-prescribing-information.pdf>

Farkas, H. et al. "International Consensus on The Diagnosis and Management of Pediatric Patients with Hereditary Angioedema with C1 Inhibitor Deficiency". Allergy, vol 72, no. 2, 2016, pp. 300-313. Wiley, doi:10.1111/all.13001. Accessed 8 May 2019.

Firazyr (icatibant) [package insert]. Lexington, MA: Shire Orphan Therapies LLC; January 2024. http://pi.shirecontent.com/PI/PDFs/Firazyr_USA_ENG.pdf

Haegarda (C1 Esterase Inhibitor Subcutaneous – Human) [package insert]. Kankakee, IL: CSL Behring LLC; January 2022. <https://labeling.cslbehring.com/PI/US/HAEGARDA/EN/HAEGARDA-Prescribing-Information.pdf>

Kalbitor (ecallantide) [package insert]. Lexington, MA: Dyax Corp.; November 2021. https://www.shirecontent.com/PI/PDFs/Kalbitor_USA_ENG.pdf

Maurer, M. et al. "The International WAO/EAACI Guideline For The Management Of Hereditary Angioedema-The 2017 Revision And Update". Allergy, vol 73, no. 8, 2018, pp. 1575-1596. Wiley, doi:10.1111/all.13384. Accessed 8 May 2019.

Orladeyo (berotralstat) [package insert]. Durham, NC: BioCryst Pharmaceuticals, Inc; ~~December~~ ~~November~~ 202~~5~~³. https://biocryst.com/wp-content/uploads/2020/12/ORLADEYO_PI_V1_2020.pdf

Ruconest (C1 Esterase Inhibitor – Recombinant) [package insert]. Bridgewater, NJ: Pharming Healthcare Inc.; April 2020. https://www.ruconest.com/wp-content/uploads/Ruconest_PI_Apr2020.pdf

Takhzyro (lanadelumab-flyo) [package insert]. Lexington, MA: Dyax Corp.; February 2023. https://www.shirecontent.com/PI/PDFs/TAKHZYRO_USA_ENG.pdf

Revision / Date	Implementation Date
Policy created	July 2019
Updated age requirement for Haegarda®, formatting changes, updated references / October 2020	April 2021
Added Orladeyo® with reference, added non-preferred wording / May 2021	July 2021
Updated age requirement for Takhzyro™, updated references / February 2023	July 2023
Formatting changes, updated references / May 2024	July 2024
Added Dawnzera™ and Ekterly® / March 2026	April 2026
<u>Updated age requirement for Orladeyo®, updated references / February 2026</u>	<u>July 2026</u>