

Policy Name:	Elaprase (idursulfase)
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Policy #:	2473P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Elaprase.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Elaprase under the Specialty Medical benefit when the following criteria have been met.

Criteria

1. Coverage Criteria for the Treatment of mucopolysaccharidosis type II (MPS type II)

- 1.1 Diagnosis of MPS type II (Hunter Syndrome)
- 1.2 Age 5 years or older
- 1.3 Prescribed by a geneticist (gene specialist)

2. Exclusion Criteria

- 2.1 Health Alliance does not cover Elaprase for pediatric patients between the ages of 16 months to 5 years because in clinical trials Elaprase did not show improvement in disease-related symptoms or long-term clinical result.

3. Approval Period

- 3.1 Initial: 12 months
- 3.2 Reauthorization: 12 months with documented clinical benefit from therapy

CPT Codes

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HCPCS Codes

J1743	Injection, idursulfase, 1mg (Elaprase)
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References

1. Elaprase (idursulfase) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals USA Inc: September 2021.
2. da Silva EM, Strufaldi MW, Andriolo RB, Silva LA. Enzyme replacement therapy with idursulfase for mucopolysaccharidosis type II (Hunter syndrome). Cochrane Database Syst Rev 2016; 2:CD008185.
3. Muenzer J, Wraith JE, Beck M, et al. A Phase II/III Clinical Study of Enzyme Replacement Therapy With Idursulfase in Mucopolysaccharidosis II (Hunter Syndrome). Genet Med, 2006, 8(8):465-73.
4. Wikman-Jorgensen PE, López Amorós A, Peris García J, et al. Enzyme replacement therapy for the treatment of Hunter disease: A systematic review with narrative synthesis and meta-analysis. Mol Genet Metab 2020; 131:206.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.

