

Policy Name:	Carbaglu (carglumic acid)	Policy #:	1781P
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Purpose of the Policy

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

Statement of the Policy

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

Criteria

1. Coverage Criteria

- 1.1 Documented diagnosis of one of the following:
 - N-acetylglutamate synthase (NAGS) deficiency confirmed by enzyme essays which demonstrate a deficiency of NAGS enzyme activity or by DNA testing
 - Methylmalonic acidemia (MMA)
 - Propionic academia (PA)
- 1.2 Medication is ordered by a physician experienced in metabolic disorders
- 1.3 Coverage of brand Carbaglu requires trial or clinical contraindication to generic carglumic acid tablets

2. Approval Period

- 2.1 Initial: 12 months
- 2.2 Reauthorization: 12 months with documented clinical benefit from therapy

CPT Codes

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HCPCS Codes

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References

1. Carbaglu (carglumic acid) [prescribing information]. Lebanon, NJ: Recordati Rare Diseases Inc; January 2024.
2. Daniotti M, la Marca G, Fiorini P, Filippi L. New developments in the treatment of hyperammonemia: emerging use of carglumic acid. *Int J Gen Med* 2011; 4:21.
3. Thompson CA. Carglumic acid approved to treat genetic hyperammonemia. *Am J Health Syst Pharm* 2010; 67:690.

4. Baumgartner MR, Hörster F, Dionisi-Vici C, et al. Proposed guidelines for the diagnosis and management of methylmalonic and propionic acidemia. *Orphanet J Rare Dis.* 2014;9:130.
5. Fraser JL, Venditti CP. Methylmalonic and propionic acidemias: clinical management update. *Curr Opin Pediatr.* 2016;28(6):682-693

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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.