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| Policy Name: | Kepivance (palifermin) | Policy#: | 3215P |
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Purpose of the Policy

The purpose of this policy is to define coverage criteria for Kepivance (palifermin).

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Kepivance (palifermin) under the specialty medical benefit if the following criteria are met.

Criteria

1. Coverage Criteria

- 1.1 Diagnosis of severe oral mucositis or at risk of developing \geq WHO Grade 3 mucositis
- 1.2 Diagnosis of blood related cancer
- 1.3 Patient is currently receiving cancer treatment that causes a decreased immune system response and requiring autologous (cells from same person) stem cell transplant support
- 1.4 Prescribed by or in consultation with an oncologist (cancer doctor) or hematologist (blood doctor)

2. Exclusion Criteria

- 2.1 Use in patients with non-blood related cancers
 - Safety and efficacy have not been established for non-blood related cancers
- 2.2 Use in patients receiving allogeneic (cells from a different person) stem cell transplant
 - Kepivance was not effective in decreasing the incidence of severe mucositis in the setting of allogeneic stem cell transplant support

3. Approval Period

- 3.1 12 months

CPT Codes

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HCPCS Codes

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| J2425 | Injection, palifermin, 50 micrograms |
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References

1. Kepivance (palifermin) [prescribing information]. Stockholm, Sweden: Swedish Orphan Biovitrum AB; September 2023.
2. Lauritano D, Petrucci M, Di Stasio D, Lucchese A. Clinical effectiveness of palifermin in prevention and treatment of oral mucositis in children with acute lymphoblastic leukemia: a case-control study. *Int J Oral Sci.* 2014;6(1):27-30.

3. Sung L, Robinson P, Treister N, et al. Guideline for the prevention of oral and oropharyngeal mucositis in children receiving treatment for cancer or undergoing haematopoietic stem cell transplantation. *BMJ Support Palliat Care*. 2017;7(1):7-16.
4. Patel P, Robinson PD, Baggott C, et al. Clinical practice guideline for the prevention of oral and oropharyngeal mucositis in pediatric cancer and hematopoietic stem cell transplant patients: 2021 update. *Eur J Cancer*. 2021;154:92-101.

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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.