UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2279-4
Program	Prior Authorization/Medical Necessity
Medication	Vijoice® (alpelisib)
P&T Approval Date	6/2022, 6/2023, 6/2024, 6/2025
Effective Date	9/1/2025

1. Background:

Vijoice® (alpelisib) is a kinase inhibitor indicated for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Vijoice** will be approved based on **ALL** of the following criteria:

   a. Diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS)

   -AND-

   b. **One** of the following criteria:

      (1) Confirmed presence of a mutation in the PIK3CA gene

      -OR-

      (2) **One** of the following:

         (a) **Two** or more of the following spectrum features:
            i. Overgrowth: adipose, muscle, nerve, skeletal
            ii. Vascular malformations: capillary, venous, arteriovenous, lymphatic
            iii. Epidermal nevus

         -OR-

         (b) **One** or more of the following isolated features:
            i. Large isolated lymphatic malformation
            ii. Isolated macrodactyly or overgrown splayed feet/ hands with overgrown limbs
            iii. Truncal adipose overgrowth
            iv. Hemimegalencephaly (bilateral) / dysplastic megalencephaly / focal cortical dysplasia
            v. Epidermal nevus

vi. Seborrheic keratoses
vii. Benign lichenoid keratoses

-AND-

c. Patient is 2 years of age or older

-AND-

d. Patient has severe manifestations of PROS requiring systemic therapy

-AND-

e. Prescribed by, or in consultation with, a clinical geneticist or a practitioner who has specialized expertise in the management of PROS manifestations

Authorization will be issued for 12 months.

B. <u>Reauthorization</u>

1. **Vijoice** will be approved based on **both** of the following criteria:

   a. Documentation of positive clinical response to **Vijoice** therapy

   -AND-

   b. Prescribed by, or in consultation with, a clinical geneticist or a practitioner who has specialized expertise in the management of PROS manifestations

   Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Vijoice [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2024.
2. Keppler-Noreuil, K. M., Rios, J. J., Parker, V. E., Semple, R. K., Lindhurst, M. J., Sapp, J. C., Alomari, A., Ezaki, M., Dobyns, W., & Biesecker, L. G. (2015). PIK3CA-related overgrowth spectrum (PROS): diagnostic and testing eligibility criteria, differential diagnosis, and evaluation.

American journal of medical genetics. Part A, 167A(2), 287–295. https://doi.org/10.1002/ajmg.a.36836

3. Venot, Q., Blanc, T., Rabia, S. H., Berteloot, L., Ladraa, S., Duong, J. P., Blanc, E., Johnson, S. C., Hoguin, C., Boccara, O., Sarnacki, S., Boddaert, N., Pannier, S., Martinez, F., Magassa, S., Yamaguchi, J., Knebelmann, B., Merville, P., Grenier, N., Joly, D., … Canaud, G. (2018). Targeted therapy in patients with PIK3CA-related overgrowth syndrome. Nature, 558(7711), 540–546. https://doi.org/10.1038/s41586-018-0217-9

Program	Prior Authorization/Medical Necessity- Vijoice® (alpelisib)
Change Control	
6/2022	New program.
6/2023	Annual review. Updated references.
6/2024	Annual review. Revised criteria for presumptive PROS if unable to confirm PIK3CA gene mutation. Updated initial authorization to 12 months. Updated references.
6/2025	Annual review without changes to coverage criteria.