Natpara (parathyroid hormone)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Natpara (parathyroid hormone)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Natpara (parathyroid hormone) may be approved when the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Documentation is provided that individual has a diagnosis of chronic (duration of greater than or equal to 18 months, Mannstadt et. al. 2013) hypoparathyroidism; **AND**
III. Individual is using as adjunct therapy to calcium supplementation and active form of a vitamin D metabolite or analog to treat hypocalcemia.

Natpara (parathyroid hormone) may not be approved for any of the following:

I. Individual has serum corrected total calcium levels maintained within therapeutic range on calcium supplements and active vitamin D forms alone; **OR**
II. A serum corrected total calcium level of less than or equal to 7.5 mg/dL at initiation of therapy; **OR**
III. Individual is using to treat hypoparathyroidism caused by a gene mutation in the calcium-sensing receptor; **OR**
IV. Individual is using to treat acute (duration of less than 6 months, Bilezikian et al. 2011) postoperative hypoparathyroidism; **OR**
V. Individual is at increased risk for osteosarcoma (such as but not limited to, concomitant Paget's disease of bone, open epiphyses, prior history of skeletal external beam or implant radiation therapy).

Note: Natpara (parathyroid hormone) has a black box warning for the risk of osteosarcoma. In male and female rats, parathyroid hormone caused an increase in the incidence of osteosarcoma (a malignant bone tumor). The occurrence of osteosarcoma was observed to be dependent on parathyroid hormone dose and treatment duration. Because of a potential risk of osteosarcoma, use Natpara only in patients who cannot be well-controlled on calcium supplements and active forms of vitamin D alone and for whom the potential benefits are considered to outweigh this potential risk. The use of Natpara should be avoided in those at increased risk for osteosarcoma, such as but not limited to individuals with Paget's disease of the bone or open epiphyses. Natpara is available only through a restricted REMS program http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=343.

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Key References:

1. Bilezikian JP, Khan A, Potts Jr JT, et al. Hypoparathyroidism in the adult: epidemiology, diagnosis, pathophysiology, target-organ involvement, treatment, and challenges for future research. *J Bone Miner Res*. 2011; 26(10):2317-2337. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3405491/.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
6. Mannstadt M, Clarke BL, Vokes T, et al. Efficacy and safety of recombinant human parathyroid hormone (1–84) in hypoparathyroidism (REPLACE): a double-blind, placebo-controlled, randomised, phase 3 study. *Lancet Diabetes Endocrinol*. 2013; 1(4): 275-283. DOI: http://dx.doi.org/10.1016/S2213-8587(13)70106-2.
7. Natpara [Package insert]. Bedminster, NJ. NPS Pharmaceuticals, Inc.; 2016. Available from: https://www.shirecontent.com/PI/PDFs/Natpara_USA_ENG.pdf

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.