Time-Sensitive Information Regarding Your Patients Receiving NATPARA 75-mcg or NATPARA 100-mcg

February 5, 2021

Dear Healthcare Provider,

The purpose of this letter is to inform you of a potential short-term supply interruption for some patients receiving NATPARA 75-mcg or NATPARA 100-mcg through the Special Use Program (SUP). An inventory processing delay, compounded by a severe winter storm during the week of February 1, 2021, has impacted the NATPARA® (parathyroid hormone) shipping schedule. There are some patients who could experience a brief supply interruption of NATPARA 75-mcg or NATPARA 100-mcg between now and the end of the second week of February. It is therefore with a sense of urgency that we are contacting you at this time. Pending any additional unanticipated delays, we have already rescheduled shipments and expect the supply interruption to be fully addressed by February 11.

This short-term supply interruption is NOT the result of any quality or manufacturing issues. This situation is not impacting NATPARA 50-mcg or NATPARA 25-mcg. However, based on the supply demands of the Special Use Program, we continue to closely monitor all NATPARA doses. We are committed to supply continuity and will provide a general update on all NATPARA doses by the end of March 2021.

Takeda's OnePath Patient Support Managers are reaching out to all impacted patients directly to emphasize the urgency of contacting their prescribing physicians to discuss the best treatment approach. OnePath is also contacting physicians whose patients may require an alternate treatment plan. Based on your independent medical judgement, if your revised treatment plan requires a new prescription, please contact Takeda OnePath at 866-888-0660 as soon as possible for your patient to receive a 7-day supply of the back-up prescription. After resolution of the supply interruption, a OnePath Patient Support Manager will follow up with you to confirm that we should resume shipments according to the patient's current prescription.

If based on previous communication of a potential for supply interruption, you had already submitted a prescription form modifying the dose for a patient currently receiving NATPARA 75-mcg or NATPARA 100-mcg, there's nothing more to do at this time. This updated prescription form will be processed in advance of the patient's supply interruption. A Takeda OnePath® Patient Support Manager will follow up with the patient and answer questions related to supply and the SUP.

For any of your patients who may be affected by a NATPARA dose interruption, please review Section 2.6 (NATPARA Dose Interruption or Discontinuation) and Section 5.4 (Warnings and Precautions: Hypocalcemia) in the attached NATPARA Full Prescribing Information. It is very important to closely monitor serum calcium levels and observe for signs and symptoms of hypocalcemia in these patients while carefully adjusting active vitamin D and supplemental calcium doses. Some patients may require higher doses of active vitamin D and supplemental calcium than doses required prior to starting NATPARA. Additional guidance regarding NATPARA treatment interruption was previously issued in a joint statement by the Endocrine Society and American Society for Bone and Mineral Research (ASBMR) at the following URL: https://endocrinenews.endocrine.org/endocrine-society-asbmr-issue-joint-statement-on-natpara-recall/.

Compliance with Special Use Program Terms & Conditions
It is important to remind SUP-enrolled patients that each NATPARA cartridge under the Special Use Program (single dose use) is intended for one use only, and that used cartridges with remaining product are to be returned to Takeda in accordance with the Special Use Program (single dose use) instructions. Non-compliance with the rules under the Special Use Program (single dose use) could result in termination of the patient's ability to receive NATPARA product through the program.

Reporting Adverse Events
Healthcare providers and patients are encouraged to report adverse events in patients taking NATPARA to Takeda at 1-800-828-2088. You are encouraged to report negative side effects of prescription drugs to the U.S. Food & Drug Administration (FDA). Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Medical Information
You may also contact our medical information department at 1-877-TAKEDA-7 (1-877-825-3327) if you have any questions about the information contained in this letter or the safe and effective use of NATPARA.

This letter is not intended as a complete description of the benefits and risks related to the use of NATPARA. Please refer to the enclosed full Prescribing Information and Medication Guide. For additional information, please call Takeda at 1-877-TAKEDA-7 (1-877-825-3327) or visit www.natpara.com.

We recognize the important medical need that NATPARA fills for your hypoparathyroidism patients. While we focus on ensuring supply continuity for SUP-enrolled patients, we continue to prioritize the goal of safely bringing NATPARA back to the broader patient community with U.S. Regulatory Authority oversight.

Sincerely,

Tom Koutsavlis
Head, US Medical

Enclosure: NATPARA Full Prescribing Information

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