

Initial REMS Approval: 01/2015

Modified REMS: 09/2016

BLA 125511

NATPARA[®] (parathyroid hormone) for injection

Recombinant human parathyroid hormone (1-84)

Shire

300 Shire Way

Lexington, MA 02421

(617) 349-0200

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL

The goal of the NATPARA REMS Program is to mitigate the potential risk of osteosarcoma associated with NATPARA by:

- a. ensuring that prescribers are educated on the following:
 - potential risk of osteosarcoma associated with the use of NATPARA
 - appropriate patient selection
 - safe-use conditions required for prescribing NATPARA
- b. ensuring that NATPARA is dispensed only to patients informed about the potential risk of osteosarcoma associated with the use of NATPARA

II. REMS Elements

A. Elements to Assure Safe Use (ETASU)

1. Healthcare providers who prescribe NATPARA are specially certified.

- a. To become specially certified to prescribe NATPARA in the NATPARA REMS Program, healthcare providers must:
 - i. Review the Prescribing Information for NATPARA.
 - ii. Review the *NATPARA REMS Program: An Introduction*.
 - iii. Review and successfully complete the *NATPARA REMS Program Training Module for Prescribers* including the *Knowledge Assessment*.
 - iv. Enroll in the NATPARA REMS Program by completing the *NATPARA REMS Program Prescriber Enrollment Form*
 - v. Agree on the *NATPARA REMS Program Prescriber Enrollment Form* to:
 - 1) Review the *NATPARA REMS Program Patient Brochure* with each patient to inform patients about the appropriate use and risks associated with NATPARA, and provide the patient a copy.
 - 2) Complete and sign the *NATPARA REMS Program Patient-Prescriber Acknowledgment Form* for each patient receiving a prescription for NATPARA. The prescriber must send a copy of the signed *NATPARA REMS Program Patient-Prescriber Acknowledgment Form* to the NATPARA REMS Program Coordinating Center by fax at 1-844-NAT-REMS (628-7367) or scan and email to NATPARAREMS@shire.com and store a copy of the form in the patient's record.
- b. Shire must:
 - i. Ensure that healthcare providers who prescribe NATPARA are specially certified, in accordance with the requirements described above.
 - ii. Provide all the following mechanisms for healthcare providers to complete the certification process for NATPARA REMS Program: online, fax, email.

- iii. Ensure that healthcare providers are notified when they have been certified by the NATPARA REMS Program.
- iv. Maintain a validated, secure database of healthcare providers who are certified to prescribe NATPARA in the NATPARA REMS Program.
- v. Ensure that healthcare providers meet the REMS certification requirements and de-certify healthcare providers who do not maintain compliance with prescriber certification requirements.
- vi. Provide the *NATPARA REMS Program: An Introduction* information sheet, *NATPARA REMS Program Training Module for Prescribers*, *NATPARA REMS Program Prescriber Enrollment Form*, *NATPARA REMS Program Patient Brochure*, *NATPARA REMS Program Patient-Prescriber Acknowledgment Form*, and the Prescribing Information to healthcare providers who (1) attempt to prescribe NATPARA and are not yet certified, or (2) inquire about how to become certified.
- vii. Ensure that REMS materials are available on the NATPARA REMS Program website (www.NATPARAREMS.com) or by calling the NATPARA REMS Program Coordinating Center at 1-855-NATPARA (628-7272).

The following materials are part of the NATPARA REMS Program and are appended:

- *NATPARA REMS Program: An Introduction*
- *NATPARA REMS Program Training Module for Prescribers*
- *NATPARA REMS Program Prescriber Enrollment Form*
- *NATPARA REMS Program Patient Brochure*
- *NATPARA REMS Program Patient-Prescriber Acknowledgment Form*

2. Pharmacies that dispense NATPARA are specially certified.

- a. To become specially certified to dispense NATPARA in the NATPARA REMS Program, pharmacies must:
 - i. Designate an authorized representative to complete the certification process on behalf of the pharmacy.

- ii. Ensure the authorized representative must oversee implementation and compliance with the NATPARA REMS Program requirements by:
 - 1) Reviewing the Prescribing Information for NATPARA.
 - 2) Reviewing the *NATPARA REMS Program: An Introduction*.
 - 3) Reviewing and successfully completing the *NATPARA REMS Program Training Module for Pharmacy Representatives*, including the *Knowledge Assessment*.
 - 4) Completing the *NATPARA REMS Program Pharmacy Enrollment Form*.
 - 5) Ensuring that all relevant staff involved in the dispensing of NATPARA are trained on the NATPARA REMS Program requirements as described in the *NATPARA REMS Program Training Module for Pharmacy Representatives*.
 - 6) Putting processes and procedures in place, and following such processes and procedures, to ensure the following requirements are completed prior to dispensing NATPARA:
 - a) Verifying that the prescriber is certified in the NATPARA REMS Program by reviewing the prescriber's information against a list of REMs certified prescribers sent from the NATPARA REMS Program Coordinating Center.
 - b) Verifying that a *NATPARA REMS Program Patient-Prescriber Acknowledgment Form* has been completed and submitted by verifying that the patient and the prescriber are included in a list of REMS-approved patients and prescribers available through the NATPARA REMS Program Coordinating Center.
- iii. Agree to be audited by Shire, FDA, or a third party to ensure that all training, processes and procedures are in place and are being followed for the NATPARA REMS Program and appropriate documentation is maintained and available upon request.
- iv. Provide prescription data to the NATPARA REMS Program.

- v. Refrain from reselling or transferring NATPARA to other pharmacies or distributors.
 - vi. Recertify in the NATPARA REMS Program if the pharmacy designates someone else as the authorized representative.
- b. A Pharmacy must dispense NATAPRA to a patient only after verifying a *NATPARA REMS Program Patient-Prescriber Acknowledgment Form* is on record and the prescribing healthcare provider is certified in the NATPARA REMS Program.
- c. Shire must:
- i. Ensure that NATPARA is dispensed only by pharmacies that are specially certified.
 - ii. Provide all the following mechanisms for pharmacies to complete the certification process for the NATPARA REMS Program: fax or email.
 - iii. Ensure that the authorized representative is notified when the pharmacy has been certified by the NATPARA REMS Program.
 - iv. Ensure that certified pharmacies are provided a list daily of certified prescribers and records documenting receipt of *NATPARA REMS Program Patient-Prescriber Acknowledgment Forms*.
 - v. Verify every 2 years that the authorized representative's name and contact information corresponds to that of the current designated authorized representative for the certified pharmacy. If different, the pharmacy must be required to re-certify with a new appointed authorized representative.
 - vi. Provide the *NATPARA REMS Program: An Introduction*, *NATPARA REMS Program Training Module for Pharmacy Representatives*, *NATPARA REMS Program Pharmacy Enrollment Form*, and the Prescribing Information to pharmacies that inquire about how to become certified.

The following materials are part of the NATPARA REMS Program and are appended:

- *NATPARA REMS Program Training Module for Pharmacy Representatives*
- *NATPARA REMS Program Pharmacy Enrollment Form*

3. NATPARA must be dispensed to patients with evidence or other documentation of safe-use conditions.

- a. NATPARA must be dispensed only to patients who have been counseled about the potential risk of osteosarcoma and completed and signed a *NATPARA REMS Program Patient-Prescriber Acknowledgment Form*.
- b. Shire must:
 - i. Ensure that the certified prescriber is able to submit the completed *NATPARA REMS Program Patient-Prescriber Acknowledgment Form* to the NATPARA REMS Program Coordinating Center by fax at 1-844-NAT-REMS (628-7367), or scan and email to NATPARAREMS@shire.com.
 - ii. Ensure that the certified pharmacy is able to verify prior to dispensing that each patient prescribed NATPARA has completed and signed a *NATPARA REMS Program Patient-Prescriber Acknowledgment Form*.

B. Implementation System

1. Shire must ensure that NATPARA is distributed to and dispensed only by certified pharmacies by:
 - a. Ensuring that wholesalers/distributors who distribute NATPARA to certified pharmacies comply with the program requirements for wholesalers/distributors. In order for a wholesalers/distributor to distribute NATPARA, the wholesalers/distributor must:
 - i. Put processes and procedures in place to verify, prior to distributing NATPARA, that the pharmacies are certified.
 - ii. Train all relevant staff on the NATPARA REMS Program requirements.

- iii. Agree to be audited by Shire, FDA, or a third party to ensure that all processes and procedures are in place and are being followed for the NATPARA REMS Program and appropriate documentation is maintained and available upon request.
 - iv. Provide distribution data to the NATPARA REMS Program.
 2. Ensuring that wholesalers/distributors maintain distribution records of all shipments of NATPARA to certified pharmacies and provide the data to the NATPARA REMS Program Coordinating Center. Shire must send the distributors/wholesalers a list of certified pharmacies every month or anytime there is a new certified pharmacy added.
 3. Shire must monitor distribution data and audit the wholesalers/distributors within 180 days after the first shipment of NATPARA by wholesaler/distributor to ensure that all processes and procedures are in place and functioning to support the requirements of the NATPARA REMS Program. Corrective action must be instituted by Shire if noncompliance is identified.
 4. Shire must send confirmation of certification to each certified pharmacy.
 5. Shire must monitor and audit certified pharmacies within 30 days after the pharmacy is certified to ensure that all processes and procedures are in place and functioning to support the requirements of the NATPARA REMS Program. Corrective action must be instituted by Shire if noncompliance is identified. The certified pharmacy must also be included in Shire ongoing annual audit plan.
 6. Shire must maintain a validated, secure database of pharmacies that are certified to dispense NATPARA in the NATPARA REMS Program.
 7. Shire must maintain adequate records of NATPARA distribution/dispensing, certified prescribers, pharmacies, health care settings, distributors/wholesalers, and patients, to meet REMS requirements.

8. Shire must ensure that the REMS requirements are met and de-certify pharmacies that do not maintain compliance with pharmacy certification requirements.
9. Shire must maintain a NATPARA REMS Program Coordinating Center (1-855-NATPARA (628-7272)) with a call center to support patients, prescribers, and pharmacies in interfacing with the NATPARA REMS Program.
10. Shire must maintain a NATPARA REMS Program Website (www.NATPARAREMS.com). The NATPARA REMS Program Website must include the capability to complete prescriber certification online. The NATPARA REMS Program Website must include the option to print the prescribing information, Medication Guide, and NATPARA REMS Program materials. The NATPARA product website must include a prominent REMS-specific link to NATPARA REMS Program Website.
11. Shire must ensure that within 60 calendar days of the approval of the REMS modification that the NATPARA REMS Program Website is fully operational and the REMS materials listed in or appended to the NATPARA REMS Document are available through the NATPARA REMS Program Website or by calling the NATPARA REMS Program Coordinating Center.
12. Shire must take reasonable steps to improve implementation of and compliance with the requirements in the NATPARA REMS Program based on monitoring and evaluation of the NATPARA REMS Program.

C. Timetable for Submission of Assessments

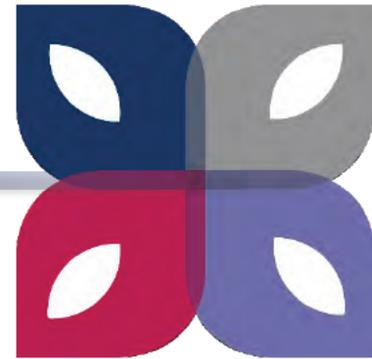
Shire must submit REMS Assessments to FDA at 6 months, 12 months, and annually thereafter from the date of initial approval of the NATPARA REMS. To facilitate inclusion of as much information as possible, while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment

should conclude no earlier than 60 days before the submission date for that assessment. Shire must submit each assessment so that it will be received by FDA on or before the due date.

NATPARA[®] (parathyroid hormone) for injection

**Risk Evaluation and Mitigation Strategy (REMS)
Program**

PRESCRIBER TRAINING MODULE



Contents



Introduction

NATPARA[®] (parathyroid hormone) for injection

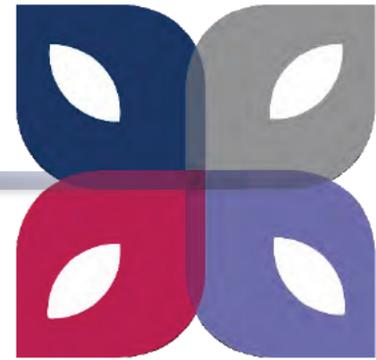
- Indication
- **Boxed Warning:** Potential Risk of Osteosarcoma
- Appropriate Patient Selection

NATPARA REMS Program Information

Questions about the NATPARA REMS Program

Knowledge Assessment

Introduction

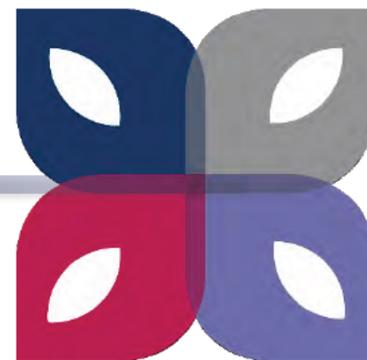


Introduction



- NATPARA is available only through a restricted program called the NATPARA REMS (Risk Evaluation and Mitigation Strategy) Program
 - Prescribers must become certified in the NATPARA REMS Program to be able to prescribe NATPARA
 - Pharmacies must be certified to dispense NATPARA
 - NATPARA must be dispensed only to patients informed about the potential risk of osteosarcoma associated with the use of NATPARA

NATPARA[®]
(parathyroid hormone) for injection



Indication



NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.

- NATPARA is not a parathyroid hormone replacement
 - Limitations of Use:
 - Because of the potential risk of osteosarcoma, NATPARA is recommended only for patients who cannot be well-controlled on calcium and active forms of vitamin D alone
 - NATPARA was not studied in patients with hypoparathyroidism caused by calcium sensing receptor mutations
 - NATPARA was not studied in patients with acute post-surgical hypoparathyroidism

Boxed Warning



WARNING: POTENTIAL RISK OF OSTEOSARCOMA

- NATPARA causes an increase in the incidence of osteosarcoma in rats
- The increase in rats is dependent on NATPARA dose and treatment duration

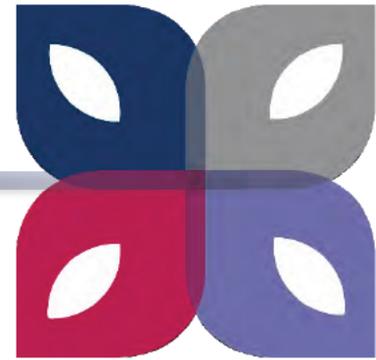
Report suspected adverse reactions to Shire at 1-855-NATPARA (1-855-628-7272) or to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Appropriate Patient Selection



- Due to the potential risk of osteosarcoma, NATPARA is only recommended for patients who cannot be well-controlled on calcium and active forms of vitamin D alone and for whom the potential benefits are considered to outweigh this potential risk.
- Avoid use of NATPARA in patients who are at increased risk for osteosarcoma, such as:
 - Patients with Paget’s disease of bone or unexplained elevations of alkaline phosphatase
 - Pediatric and young adult patients with open epiphyses
 - Patients with hereditary disorders predisposed to osteosarcoma
 - Patients with a prior history of external beam or implant radiation therapy involving the skeleton

NATPARA REMS Program Information



NATPARA REMS Program Information



Program Overview

- Prescriber Certification
 - Certification consists of training, including successful completion of the Knowledge Assessment and enrolling in the NATPARA REMS Program
- Patient counseling on benefits and risks of NATPARA
- Completion of one-time NATPARA *REMS Program Patient-Prescriber Acknowledgment Form* – required before NATPARA can be dispensed from pharmacy
- Only certified pharmacies can dispense NATPARA

NATPARA REMS Program



To become certified in the NATPARA REMS program, prescribers must complete the following steps:

1. Review the following:
 - NATPARA Prescribing Information
 - NATPARA *REMS Program: An Introduction*
 - NATPARA *REMS Program Training Module for Prescribers*
2. Successfully complete and submit the Knowledge Assessment at the end of this training module
3. Complete, sign, and submit the one-time NATPARA *REMS Program Prescriber Enrollment Form*

Prescriber Certification and Enrollment Process



Prescriber certification and enrollment can be completed either online or through a paper-based process:

1) Online

- Visit www.NATPARAREMS.com and click on the “Prescriber Certification” tab for online certification and enrollment instructions

2) Paper-based

- Review the NATPARA Prescribing Information, *NATPARA REMS Program: An Introduction*, and the *NATPARA REMS Program Training Module for Prescribers*
- Complete and submit both the Knowledge Assessment section from the *NATPARA REMS Program Training Module for Prescribers* and the *NATPARA REMS Program Prescriber Enrollment Form* to the NATPARA REMS Program Coordinating Center via:
 - Fax at 1-844-NAT-REMS (628-7367) or
 - Scan and email to NATPARAREMS@shire.com

REMS materials may be downloaded from the REMS website at www.NATPARAREMS.com; alternatively you may request hard copies by calling 1-855-NATPARA (628-7272)

Patient Counseling on Benefit/Risk Profile



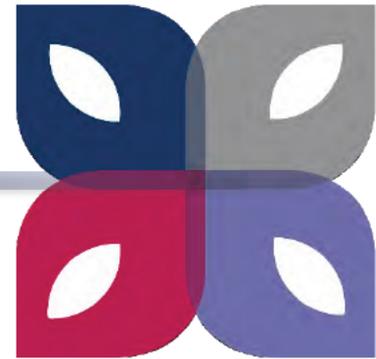
- Prescriber must counsel patients on the benefit/risk profile of NATPARA
 - The NATPARA *REMS Program Patient-Prescriber Acknowledgment Form* contains information on benefit and risks of NATPARA in patient-friendly language to counsel your patients
 - Provide patients with copies of the NATPARA *REMS Program Patient Brochure* and the NATPARA *REMS Program Patient-Prescriber Acknowledgment Form*

Prescription Process



- Complete and sign the *NATPARA REMS Program Patient-Prescriber Acknowledgment Form* with each patient prior to initiation of therapy
- Provide patients with a copy of the signed form and a copy of the *NATPARA REMS Program Patient Brochure*
- Submit the *NATPARA REMS Program Patient-Prescriber Acknowledgment Form* and prescription for NATPARA to the NATPARA REMS Program Coordinating Center by fax at 1-844-NAT-REMS (628-7367) or scan and email to NATPARAREMS@shire.com
- The NATPARA REMS Program Coordinating Center will send the prescription to a certified pharmacy to fill after verifying that the prescriber is certified and a *NATPARA REMS Program Patient-Prescriber Acknowledgment Form* is on record
- Certified pharmacies will not dispense NATPARA if a prescriber is not certified and/or the *NATPARA REMS Program Patient-Prescriber Acknowledgment Form* is not on record
- The certified pharmacy will contact the patient to arrange the date to ship NATPARA once the prescription is filled

Questions about the NATPARA REMS Program

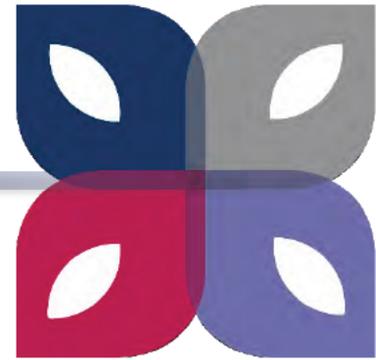


Questions about the NATPARA REMS Program



- Visit www.NATPARAREMS.com
- Call 1-855-NATPARA (628-7272)

Knowledge Assessment



Knowledge Assessment - Instructions



- You can complete the certification and enrollment process directly online at www.NATPARAREMS.com or through a paper-based process as follows:
 - Print out both pages of the Knowledge Assessment questions and the *NATPARA REMS Program Prescriber Enrollment Form*
 - Answer all questions in the Knowledge Assessment (100% passing score required)
 - Complete and sign the *NATPARA REMS Program Prescriber Enrollment Form*
 - Submit the completed Knowledge Assessment and *NATPARA REMS Program Prescriber Enrollment Form* to the NATPARA REMS Program Coordinating Center via:
 - Fax at 1-844-NAT-REMS (628-7367) or
 - Scan and email to NATPARAREMS@shire.com
- You will receive correspondence from the NATPARA REMS Program Coordinating Center on your certification status immediately (online) or within 2 business days (paper-based)

Knowledge Assessment



Complete all 7 questions. Mark only one answer for each question.
You can also complete the certification and enrollment process online at

www.NATPARAREMS.com

Question 1

NATPARA is only available through the NATPARA REMS Program.

- True
- False

Question 2

What is the approved indication statement for NATPARA?

- NATPARA is a parathyroid hormone replacement therapy indicated for the treatment of hypoparathyroidism
- NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism
- NATPARA is indicated as monotherapy for hypoparathyroidism
- NATPARA is indicated as monotherapy for hypocalcemia

Question 3

NATPARA causes an increase in the incidence of osteosarcoma in rats.

- True
- False

Question 4

Avoid use of NATPARA in patients who are at increased risk of osteosarcoma, such as:

- Patients with Paget's disease of bone or unexplained elevations in alkaline phosphatase
- Pediatric and young adult patients with open epiphyses
- Patients with hereditary disorders predisposed to osteosarcoma
- Patients with a prior history or external beam or implant radiation therapy involving the skeleton
- All of the above

Knowledge Assessment



Question 5

How often should the *Patient-Prescriber Acknowledgment Form* be completed?

- With each new prescription
- With every refill
- Once a year
- One-time for each new patient

Question 6

Patients who are controlled on a regimen of calcium and vitamin D should be switched to NATPARA.

- True
- False

Question 7

Prescribers must counsel patients on the risk/benefit profile for NATPARA.

- True
- False

If faxing your Knowledge Assessment, include your name below:

Prescriber Name: (please print)

You must complete and submit both the Knowledge Assessment and the NATPARA *REMS Program Prescriber Enrollment Form* to become certified in the NATPARA REMS Program. You can complete the certification and enrollment process online at www.NATPARAREMS.com or submit both documents via:

- Fax at 1-844-NAT-REMS (628-7367) or
- Scan and email to NATPARAREMS@shire.com

Completion of Training Module



Thank you for completing the NATPARA REMS Program Training Module.

As a reminder, you may complete the certification and enrollment process online at www.NATPARAREMS.com or through a paper-based process by completing and submitting the Knowledge Assessment and NATPARA *REMS Program Prescriber Enrollment Form* via:

- Fax: 1-844-NAT-REMS (628-7367) or
- Email: NATPARAREMS@shire.com

REMS Materials may be downloaded from the REMS website at www.NATPARAREMS.com; alternatively you may request hard copies by calling 1-855-NATPARA (628-7272)

NATPARA REMS Program: Prescriber Enrollment Form

NATPARA® (parathyroid hormone) for injection is only available through the NATPARA Risk Evaluation and Mitigation Strategy (REMS) Program. In order to prescribe NATPARA, a prescriber must:

1. Review the Prescribing Information, the NATPARA *REMS Program: An Introduction information sheet*, the NATPARA *REMS Program: Training Module for Prescribers*, and successfully complete the Knowledge Assessment.
2. Complete this one-time NATPARA *REMS Program: Prescriber Enrollment Form*.
3. Complete and submit a NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* prior to initiation of therapy for each patient.

Step 1 and 2 can be completed directly online at www.NATPARAREMS.com; or you may complete and submit this form along with the Knowledge Assessment to the NATPARA REMS Program Coordinating Center by fax at 1-844-NAT-REMS (628-7367) or scan and email to NATPARAREMS@shire.com. Please print. All information is required.

Prescriber Information

Name (first, middle, last): _____ Credentials: MD DO NP PA Other: _____

Name of Institution/Practice Name: _____

Practice Setting: Hospital-Based Practice Private/Group Practice

Physician Specialty (Board Certification):

Practice Address: _____

Endocrinology Internal Medicine

City: _____ State: _____ Zip Code: _____

Family Medicine

Other [please specify]: _____

Preferred Method of Contact: Mail Email Email Address: _____

Office Phone Number: _____ Mobile Phone Number: _____ Office Fax Number: _____

Primary State License Number/State of Issue: _____

National Provider Identification (NPI) Number: _____

Prescriber Attestation

By signing this form I attest that:

- I understand that 1) NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism 2) NATPARA is not a parathyroid hormone replacement and 3) Because of the potential risk of osteosarcoma, NATPARA is recommended only for patients who cannot be well-controlled on calcium and active forms of vitamin D alone
- I understand there is a potential risk of osteosarcoma associated with NATPARA. NATPARA causes an increase in the incidence of osteosarcoma in rats. The increase in osteosarcoma in rats is dependent on NATPARA dose and treatment duration
- I understand that NATPARA is only available through the NATPARA REMS Program and that I must comply with the program requirements in order to prescribe NATPARA
- I have reviewed the Prescribing Information, the NATPARA *REMS Program: An Introduction information sheet*, the NATPARA *REMS Program: Training Module for Prescribers*, and answered all questions included in the Knowledge Assessment
- I understand that I must counsel my patients on the benefits and risks of NATPARA treatment, sign and submit the NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form*, and provide a copy of the NATPARA *REMS Program Patient Brochure* and NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* to my patients prior to initiation of therapy
- I agree that Shire, its agents, and contractors, such as the pharmacy, may contact me via phone, mail, or email to survey me on the effectiveness of the program requirements for NATPARA REMS Program

Prescriber Signature: _____ Date: _____

(MM/DD/YY)

Print Name: _____

**If you have any questions, contact the NATPARA REMS Program Coordinating Center.
Phone: 1-855-NATPARA Fax: 1-844-NAT-REMS (628-7367) www.NATPARAREMS.com**



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NATPARA REMS Program: An Introduction

What Is the NATPARA REMS (Risk Evaluation and Mitigation Strategy) Program?

A REMS is a strategy to manage known or potential risks associated with a drug, and it is required by the FDA to ensure that the benefits of the drug outweigh its risks. NATPARA® (parathyroid hormone) for injection is available only under a restricted program called the NATPARA REMS Program because of the potential risk of osteosarcoma.

NATPARA REMS Program Requirements

- Certification of prescribers of NATPARA
- Patient counseling on the benefits and risks of NATPARA and completion of a NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* for each patient
- Only certified pharmacies can dispense NATPARA

Prescriber Certification

Prescriber certification and enrollment can be completed directly online at www.NATPARAREMS.com or through a paper-based process as follows:

1. Review the Prescribing Information, NATPARA *REMS Program: An Introduction*, and the NATPARA *REMS Program: Training module for Prescribers*.
2. Successfully complete and submit both the Knowledge Assessment section of the training module and the NATPARA *REMS Program: Prescriber Enrollment Form* via fax at 1-844-NAT-REMS (628-7367) or scan and email to NATPARAREMS@shire.com.

Patient Counseling and Patient-Prescriber Acknowledgment Form

- Counsel patients on appropriate use and the benefits and risks of NATPARA
- Download the NATPARA *REMS Program: Patient Brochure* and NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* at www.NATPARAREMS.com or request copies by calling 1-855-NATPARA (628-7272)
- Complete the NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* and NATPARA prescription. Send both to the NATPARA REMS Program Coordinating Center via fax at 1-844-NAT-REMS (628-7367) or scan and e-mail to NATPARAREMS@shire.com
- Provide patient with a copy of the NATPARA *REMS Program: Patient Brochure* and NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form*

Pharmacy Certification

Pharmacies must designate an authorized Pharmacy Representative who will complete the certification process on behalf of the pharmacy and:

1. Review the Prescribing Information and NATPARA *REMS Program: An Introduction*.
2. Successfully complete the NATPARA *REMS Program: Training Module for Pharmacy Representatives*, including the Knowledge Assessment.
3. Complete and sign the NATPARA *REMS Program: Pharmacy Enrollment Form*.
4. Implement the necessary staff training and processes to comply with the NATPARA REMS Program requirements including:
 - Receiving the prescription from the NATPARA REMS Program Coordinating Center
 - Verification that prescriber is certified in the NATPARA REMS Program
 - Verification that a NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* is on record for patient and prescriber
 - Contacting the patient to arrange the date to ship NATPARA once the prescription is filled

Visit www.NATPARAREMS.com to access training materials and enrollment forms. Or call 1-855-NATPARA.

If you have any questions, contact the NATPARA REMS Program Coordinating Center.
Phone: 1-855-NATPARA Fax: 1-844-NAT-REMS (628-7367) www.NATPARAREMS.com



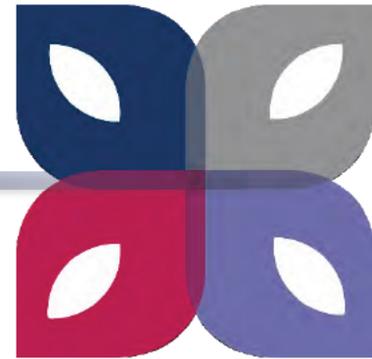
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NATPARA[®] (parathyroid hormone) for injection

**Risk Evaluation and Mitigation Strategy (REMS)
Program**

TRAINING MODULE FOR PHARMACY
REPRESENTATIVES



Contents



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NATPARA[®] (parathyroid hormone) for injection

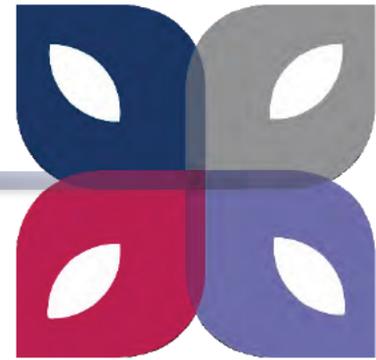
- Indication
- **Boxed Warning:** Potential Risk of Osteosarcoma
- Appropriate Patient Selection

NATPARA REMS Program Information

Questions about the NATPARA REMS Program

Knowledge Assessment

Introduction

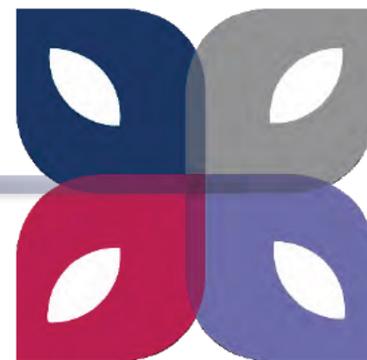


Introduction



- NATPARA is available only through a restricted program called the NATPARA REMS (Risk Evaluation and Mitigation Strategy) Program
 - Pharmacies must designate an authorized Pharmacy Representative to complete the certification in the NATPARA REMS Program in order to dispense NATPARA
 - Prescribers must be certified in the NATPARA REMS Program in order to prescribe NATPARA
 - NATPARA must be dispensed only to patients informed about the potential risk of osteosarcoma associated with the use of NATPARA

NATPARA[®]
(parathyroid hormone) for injection



Indication



NATPARA is parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.

- NATPARA is not a parathyroid hormone replacement
 - Limitations of Use:
 - Because of the potential risk of osteosarcoma, NATPARA is recommended only for patients who cannot be well-controlled on calcium and active forms of vitamin D alone
 - NATPARA was not studied in patients with hypoparathyroidism caused by calcium-sensing receptor mutations
 - NATPARA was not studied in patients with acute post-surgical hypoparathyroidism

Boxed Warning



WARNING: POTENTIAL RISK OF OSTEOSARCOMA

- NATPARA causes an increase in the incidence of osteosarcoma in rats
- The increase in rats is dependent on NATPARA dose and treatment duration

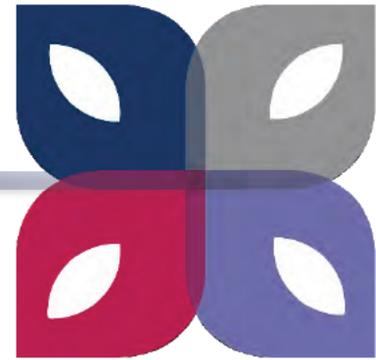
Report suspected adverse reactions to Shire at 1-855-NATPARA (1-855-628-7272) or to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Appropriate Patient Selection



- Due to the potential risk of osteosarcoma, NATPARA is only recommended for patients who cannot be well-controlled on calcium and active forms of vitamin D alone
- Avoid use of NATPARA in patients who are at increased risk for osteosarcoma, such as:
 - Patients with Paget's disease of bone or unexplained elevations of alkaline phosphatase
 - Pediatric and young adult patients with open epiphyses
 - Patients with hereditary disorders predisposed to osteosarcoma
 - Patients with a prior history of external beam or implant radiation therapy involving the skeleton

NATPARA REMS Program Information



NATPARA REMS Program Information



Program Overview

- Prescriber Certification
 - NATPARA can be prescribed only by certified prescribers
 - Prescribers will:
 - Counsel patients about the benefit/risk profile of NATPARA
 - Complete the one-time NATPARA *REMS Program Patient-Prescriber Acknowledgment Form* for each patient
- **Only certified pharmacies may dispense NATPARA**
 - Verification of prescriber certification before dispensing NATPARA
 - Verification of NATPARA *REMS Program Patient-Prescriber Acknowledgment Form* on record for the patient before dispensing NATPARA

NATPARA REMS Program



- Pharmacies must designate an **authorized pharmacy representative** who will complete the certification process on behalf of the pharmacy

NATPARA REMS Program



For your pharmacy to become certified, authorized pharmacy representatives must complete the following steps:

1. Review the following:
 - NATPARA Prescribing Information,
 - NATPARA *REMS Program: An Introduction*
 - NATPARA *REMS Program Training Module for Pharmacy Representatives*
2. Successfully complete and submit the Knowledge Assessment at the end of this training module
3. Complete, sign, and submit the NATPARA *REMS Program Pharmacy Enrollment Form*

Enroll in the NATPARA REMS Program



To enroll in the NATPARA REMS Program:

1. Answer the questions in the Knowledge Assessment section of the NATPARA REMS Program Training Module for Pharmacy Representatives
2. Find the NATPARA REMS Program Pharmacy Enrollment Form at www.NATPARAREMS.com or request a copy by calling 1-855-NATPARA (628-7272)
 - Complete and sign the enrollment form
3. Submit enrollment form and the Knowledge Assessment section to the NATPARA REMS Program Coordinating Center by:
 - Fax to 1-844-NAT-REMS (628-7367) or
 - Scan and email to NATPARAREMS@shire.com

Pharmacy Representative Responsibilities



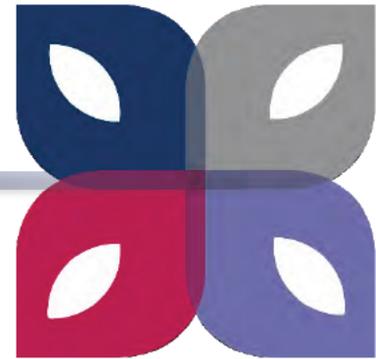
- Ensure all relevant staff involved in dispensing of NATPARA are trained on the NATPARA REMS Program requirements as described in the *NATPARA REMS Program Training Module for Pharmacy Representatives*
- Put processes and procedures in place to ensure the following verifications and safe-use conditions are met prior to dispensing NATPARA:
 - Receive the prescription from the NATPARA REMS Program Coordinating Center
 - Verify that the prescriber is certified in the NATPARA REMS program
 - Verify that a *NATPARA REMS Program Patient-Prescriber Acknowledgement Form* is on record for each patient
 - Contact the patient to arrange the date to ship NATPARA once the prescription is filled

Pharmacy Representative Responsibilities



- Make available to Shire — and/or a designated third party of the FDA — documentation to verify your understanding of and adherence to the requirements of the NATPARA REMS Program
- Recertify in the NATPARA REMS Program if the pharmacy designates someone else as the authorized representative.

Questions about the NATPARA REMS Program

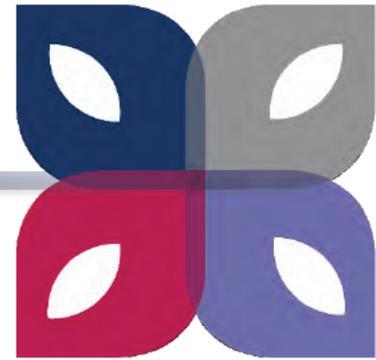


Questions about the NATPARA REMS Program



- Visit www.NATPARAREMS.com
- Call 1-855-NATPARA (628-7272)

Knowledge Assessment



Knowledge Assessment - Instructions



- To complete the certification process you will need to answer all questions in Knowledge Assessment correctly.
- Print out both pages of Knowledge Assessment questions.
- Fax your Knowledge Assessment and Enrollment Form to: **1-844-NAT-REMS (628-7367)**

Or

- Scan and email your Knowledge Assessment and Enrollment Form to: **NATPARAREMS@shire.com**
- You will receive correspondence from the NATPARA REMS Program on your certification status **within 2 business days.**

Knowledge Assessment



Complete all 5 questions.

Question 1

NATPARA is only available through the NATPARA REMS Program.

- True
- False

Question 2

What is the approved indication statement for NATPARA?

- NATPARA is a parathyroid hormone replacement therapy indicated for the treatment of hypoparathyroidism
- NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism
- NATPARA is indicated as monotherapy for hypoparathyroidism
- NATPARA is indicated as monotherapy for hypocalcemia

Question 3

NATPARA causes an increase in the incidence of osteosarcoma in rats.

- True
- False

Question 4

Avoid use of NATPARA in patients who are at increased risk of osteosarcoma, such as:

- Patients with Paget's disease of bone or unexplained elevations in alkaline phosphatase
- Pediatric and young adult patients with open epiphyses
- Patients with hereditary disorders predisposed to osteosarcoma
- Patients with a prior history or external beam or implant radiation therapy involving the skeleton
- All of the above

Knowledge Assessment



Question 5 (check all that apply)

Prior to distributing each NATPARA prescription, pharmacies need to:

- Verify that the prescriber is certified in the NATPARA REMS Program
- Verify that a NATPARA *REMS Program Patient-Prescriber Acknowledgment Form* is on record for the patient
- Call the patient to verify that counseling took place with prescriber
- All of the above

If faxing your Knowledge Assessment, include your name below:

Pharmacy Representative Name: (please print)

You must complete and submit both the Knowledge Assessment and Enrollment form for your pharmacy to become certified in the NATPARA REMS Program.

Fax to: 1-844-NAT-REMS (628-7367)

Or scan and email to: NATPARAREMS@shire.com

Completion of Training Module



Thank you for completing the NATPARA *REMS Program Training Module*.

To complete your enrollment in the NATPARA REMS Program:

- Find the NATPARA *REMS Program Pharmacy Enrollment Form* at www.NATPARAREMS.com or request a copy by calling 1-855-NATPARA (628-7272)
- Complete and sign the enrollment form
- Submit Knowledge Assessment and enrollment form:
 - Fax to 1-844-NAT-REMS (628-7367) or
 - Scan and email to NATPARAREMS@shire.com

NATPARA REMS Program: Pharmacy Enrollment Form

To become certified, the pharmacy must designate an authorized Pharmacy Representative to coordinate the setting's activities and assure compliance with the NATPARA® Risk Evaluation and Mitigation Strategy (REMS) Program.

INSTRUCTIONS:

Fax completed form to the NATPARA REMS Program Coordinating Center at 1-844-NAT-REMS (628-7367) or scan form and e-mail it to NATPARAREMS@shire.com. You will receive an enrollment confirmation within 2 business days after your form is received.

NATPARA is only available through the NATPARA REMS Program.
Because of the risk of osteosarcoma associated with NATPARA, only certified pharmacies may dispense NATPARA.

Authorized Pharmacy Representative Responsibilities

As the authorized Pharmacy Representative designated by my pharmacy to coordinate the activities of the NATPARA REMS Program, I agree to comply with the following program requirements:

1. Review the Prescribing Information and the NATPARA *REMS Program: An Introduction* information sheet.
2. Review the NATPARA *REMS Program: Training Module for Pharmacy Representatives*, and answer all questions in the Knowledge Assessment.
3. Ensure all relevant staff involved in dispensing NATPARA are trained on the NATPARA REMS Program requirements as described in the NATPARA *REMS Program: Training Module for Pharmacy Representatives*.
4. Put processes and procedures in place to ensure the following verifications and safe use conditions are met prior to dispensing NATPARA:
 - Verify that the prescriber is certified in the NATPARA REMS Program by reviewing the prescriber's information against a list of REMS certified prescribers sent from the NATPARA REMS Program Coordinating Center
 - Verify that a NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* has been completed and submitted by verifying that the patient and prescriber are included in a list of REMS approved patients and prescribers available through the NATPARA REMS Program Coordinating Center
5. Make available to Shire, and/or a designated third party of FDA, documentation to verify understanding of, and adherence to, the requirements of the NATPARA REMS Program.

Please print. All information is required.

Authorized Pharmacy Representative

Name (first, middle, last): _____

Pharmacy Name: _____

Pharmacy Address: _____

City: _____ State: _____ Zip Code: _____ Preferred Method of Contact: Mail E-mail

E-mail Address: _____ Office Phone Number: _____ Office Fax Number: _____

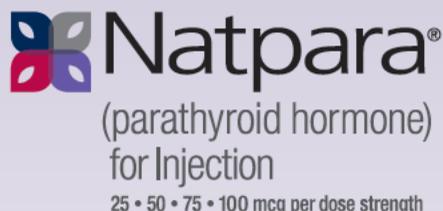
Signature: _____ Date: _____
Authorized Pharmacy Representative (MM/DD/YY)

If you have any questions, contact the NATPARA REMS Program Coordinating Center.
Phone: 1-855-NATPARA Fax: 1-844-NAT-REMS (628-7367) www.NATPARAREMS.com



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NATPARA REMS PROGRAM PATIENT BROCHURE

What you need to know about NATPARA

What is NATPARA?

NATPARA is a parathyroid hormone (PTH) used with calcium and vitamin D to control low blood calcium (hypocalcemia) in people with low PTH blood levels (hypoparathyroidism).

What is the most serious risk of NATPARA?

- Possible risk of bone cancer
- During animal drug testing, the medicine in NATPARA caused some rats to develop bone cancer called osteosarcoma. In people, osteosarcoma is a serious but rare cancer
- It is not known if people who take NATPARA will have a higher chance of getting bone cancer
- Because of the potential risk of bone cancer, NATPARA is recommended only for patients who cannot be well-controlled on calcium and active forms of vitamin D alone

What are the signs and symptoms of bone cancer?

- Pain in any areas of your body that does not go away
- Any new or unusual lumps or swelling under your skin that is tender to touch

Tell your doctor right away if you have any of these signs or symptoms.

The NATPARA REMS Program

- Because of the possible risk of bone cancer, NATPARA is only available through a special program called the NATPARA REMS (Risk Evaluation and Mitigation Strategy) Program
- Your doctor will discuss the benefits and risks of NATPARA with you
- You and your doctor will sign the NATPARA REMS Program: *Patient-Prescriber Acknowledgment Form*. You must sign this form in order to receive NATPARA

How do I receive NATPARA?

NATPARA is only available through a REMS Certified Pharmacy. The NATPARA REMS Program Coordinating Center will call you to tell you the name and phone number of the certified pharmacy that will fill your NATPARA prescription. The certified pharmacy will call you to arrange the date to ship NATPARA to you. Call the NATPARA REMS Program Coordinating Center at 1-855-NATPARA if you need assistance with your prescription.

This brochure only discusses the most serious risk of NATPARA and the NATPARA REMS Program. For more safety information about NATPARA please see the NATPARA Medication Guide available at www.NATPARAREMS.com.



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NATPARA REMS Program: Patient-Prescriber Acknowledgment Form

Instructions for Prescribers

1. Counsel the patient on the benefits and risks of NATPARA.
2. Complete each section of the form as required with the patient.
3. Provide a copy of the signed form to the patient along with a copy of the NATPARA *REMS Program Patient Brochure*.
4. Send the completed form and the patient's prescription to the NATPARA REMS Program Coordinating Center by fax to 1-844-NAT-REMS (628-7367) or e-mail to NATPARAREMS@shire.com.

Instructions for Patients

1. NATPARA is available only through a special program called the NATPARA REMS Program.
2. This form must be completed before you can receive NATPARA® (parathyroid hormone) for Injection.
3. Your prescriber will help you complete this form and will give you a copy along with a copy of the NATPARA *REMS Program Patient Brochure*.
4. The NATPARA REMS Program Coordinating Center will help you find a certified pharmacy to fill your NATPARA prescription.

Patient Demographic Information (Please Print)

Gender*: Male Female Age*: _____

Patient Acknowledgment

By signing this form, I acknowledge that:

- I have received, read, and understand the information in the NATPARA *REMS Program Patient Brochure*.
- My doctor reviewed with me the benefits and risks of treatment with NATPARA listed below and answered all my questions or concerns about my treatment with NATPARA.
- I understand that I should tell my doctor right away if I have any of the following signs or symptoms that could be associated with osteosarcoma:
 - pain in any areas of my body that does not go away
 - any new or unusual lumps or swelling under my skin that is tender to touch

Benefits:

- NATPARA is a parathyroid hormone (PTH). It is used with calcium and vitamin D to control low blood calcium (hypocalcemia) in people with low PTH blood levels (hypoparathyroidism).

Risks:

- During animal drug testing, the medicine in NATPARA caused some rats to develop a type of bone cancer called osteosarcoma. In people, osteosarcoma is a serious but rare cancer.
- It is not known if people who take NATPARA have a higher chance of getting bone cancer.
- Because of the potential risk of bone cancer, NATPARA is recommended only for patients who cannot be well-controlled on calcium and active forms of vitamin D alone.

Written Permission to Share Information

- I give permission to my healthcare provider to share this form with Shire and their Contractors to use and share my personal health information for the purposes of coordinating the dispensing of NATPARA, administering the NATPARA REMS Program, and releasing my personal health information to the Food and Drug Administration (FDA) as necessary.
- My permission lasts until the Program ends. I can cancel my permission at any time by providing written notice to my healthcare provider.

Patient/Legal Representative Signature*: _____ Date*: _____

Printed Name*: _____ (MM/DD/YY)

Prescriber Acknowledgment

I acknowledge that prior to prescribing NATPARA:

- I counseled the patient on the benefits and risks of NATPARA by reviewing the NATPARA *REMS Program Patient Brochure* and the NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form*.
- I discussed all concerns and answered any questions raised by the patient or patient representative.
- The patient or patient representative signed this NATPARA *REMS Program: Acknowledgment Form* and I provided a copy of the NATPARA *REMS Program Patient Brochure* and the signed NATPARA *REMS Program: Acknowledgment Form* to the patient.

Prescriber NPI*: _____

Signature of Prescriber*: _____

Printed Name*: _____

Date*: _____ (MM/DD/YY)

*Indicates mandatory field.

Please fax this completed form and the patient's prescription to the NATPARA REMS Program Coordinating Center at 1-844-NAT-REMS.



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NATPARA REMS Program Prescriber Certification

Prescriber certification and enrollment are required to prescribe NATPARA.

This can be completed either online or through a paper-based process.



Online Process

Click on the link below to complete the training, certification, and enrollment in the NATPARA REMS Program online:

- You will be required to enter your National Provider Identifier (NPI) number and your name as it appears in the NPI Registry
- You will be guided through the training, certification, and enrollment process
- Upon successful completion, you will become certified and enrolled in the NATPARA REMS Program

**BEGIN ONLINE PRESCRIBER
CERTIFICATION AND ENROLLMENT**



MATERIALS TO DOWNLOAD

For Prescribers

[NATPARA Prescribing Information](#)

[NATPARA REMS Program: An Introduction](#)

[Training Module and Assessment
for Prescribers](#)

[Prescriber Enrollment Form](#)

[Patient-Prescriber Acknowledgment Form and
Patient Brochure](#)

[NATPARA REMS Program FAQ](#)



Paper-based Process

Download and review the following materials:

- [Prescribing Information](#)
- [NATPARA REMS Program: An Introduction](#)
- [NATPARA REMS Program: Training Module for Prescribers](#)

Print and complete the following:

- Knowledge Assessment section from the [NATPARA REMS Program: Training Module for Prescribers](#)
- [NATPARA REMS Program: Prescriber Enrollment Form](#)

Submit the Knowledge Assessment and the [NATPARA REMS Program: Prescriber Enrollment Form](#) via:

- Fax to **1-844-NAT-REMS (628-7367)** or
- Scan and email to **NATPARAREMS@shire.com**

You may also request hard copies of the materials by calling **1-855-NATPARA (628-7272)**

A confirmation of your certification in the NATPARA REMS Program will be sent to you immediately (online) or within two (2) business days (paper-based), so you can begin to prescribe NATPARA.

Before initiating treatment, prescribers must also counsel patients on the appropriate use and the benefits and risks of NATPARA. To complete the NATPARA REMS Program requirements for prescribing NATPARA:



- Download the [NATPARA REMS Program: Patient Brochure](#) and the [NATPARA REMS Program: Patient-Prescriber Acknowledgment Form](#)
- Complete the [NATPARA REMS Program: Patient-Prescriber Acknowledgment Form](#)
- Send the patient's prescription and the [NATPARA REMS Program: Patient-Prescriber Acknowledgment Form](#) by
 - Fax to **1-844-NAT-REMS (628-7367)** or
 - Scan and e-mail to **NATPARAREMS@shire.com**
- Provide patient with a copy of the [NATPARA REMS Program: Patient Brochure](#) and the [NATPARA REMS Program: Patient-Prescriber Acknowledgment Form](#)

If you have any questions, contact the NATPARA REMS Program Coordinating Center at 1-855-NATPARA.

Prescriber Training - Identification

NPI *

First Name *

Last Name *

Submit

NATPARA REMS Program Prescriber Training

Welcome to the NATPARA REMS Program Online Prescriber Training and Certification process

PLEASE READ the **important steps** below:

1. You will review the NATPARA REMS Program training materials.
2. You will take a Knowledge Assessment consisting of **seven (7)** multiple choice and true or false questions.
 - You must achieve a **passing score of 100%**.
 - You will be allowed up to **three (3) attempts** to achieve the passing score.
 - After three (3) incorrect responses you will be **locked out** and **deemed ineligible to prescribe**. You **will not** be able to return and complete the assessment.
3. Upon successful completion of the Knowledge Assessment, you will
 - Complete the *NATPARA REMS Program Prescriber Enrollment Form*.
 - Receive a Certificate of Completion.

[Click HERE to begin](#)

NATPARA REMS Program Prescriber Training

NATPARA REMS Program: An Introduction

What Is the NATPARA REMS (Risk Evaluation and Mitigation Strategy) Program?

A REMS is a strategy to manage known or potential risks associated with a drug, and it is required by the FDA to ensure that the benefits of the drug outweigh its risks. NATPARA® (parathyroid hormone) for injection is available only under a restricted program called the NATPARA REMS Program because of the potential risk of osteosarcoma.

NATPARA REMS Program Requirements

- Certification of prescribers of NATPARA
- Patient counseling on the benefits and risks of NATPARA and completion of a NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* for each patient
- Only certified pharmacies can dispense NATPARA

Prescriber Certification

Prescriber certification and enrollment can be completed directly online at www.NATPARAREMS.com or through a paper-based process as follows:

I have reviewed the 'NATPARA REMS Program: An Introduction'

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NATPARA REMS Program Prescriber Training

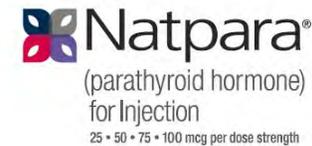
4. Implement the necessary staff training and processes to comply with the NATPARA REMS Program requirements including:
- Receiving the prescription from the NATPARA REMS Program Coordinating Center
 - Verification that prescriber is certified in the NATPARA REMS Program
 - Verification that a NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* is on record for patient and prescriber
 - Contacting the patient to arrange the date to ship NATPARA once the prescription is filled

Visit www.NATPARAREMS.com to access training materials and enrollment forms. Or call 1-855-NATPARA.

If you have any questions, contact the NATPARA REMS Program Coordinating Center.
Phone: 1-855-NATPARA Fax: 1-844-NAT-REMS (628-7367) www.NATPARAREMS.com



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I have reviewed the 'NATPARA REMS Program: An Introduction'

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NATPARA REMS Program Prescriber Training

NATPARA[®] (parathyroid hormone) for injection
**Risk Evaluation and Mitigation Strategy (REMS)
Program**



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PRESCRIBER TRAINING MODULE

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REMS Prescriber Training

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- **Boxed Warning:** Potential Risk of Osteosarcoma
- Appropriate Patient Selection

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NATPARA REMS Program Prescriber Training

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NATPARA REMS Program Prescriber Training

Introduction

- NATPARA is available only through a restricted program called the NATPARA REMS (Risk Evaluation and Mitigation Strategy) Program
 - Prescribers must become certified in the NATPARA REMS Program to be able to prescribe NATPARA
 - Pharmacies must be certified to dispense NATPARA
 - NATPARA must be dispensed only to patients informed about the potential risk of osteosarcoma associated with the use of NATPARA



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NATPARA REMS Program Prescriber Training

Indication

NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.

- NATPARA is not a parathyroid hormone replacement
 - Limitations of Use:
 - Because of the potential risk of osteosarcoma, NATPARA is recommended only for patients who cannot be well-controlled on calcium and active forms of vitamin D alone
 - NATPARA was not studied in patients with hypoparathyroidism caused by calcium sensing receptor mutations
 - NATPARA was not studied in patients with acute post-surgical hypoparathyroidism



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NATPARA REMS Program Prescriber Training

Boxed Warning

WARNING: POTENTIAL RISK OF OSTEOSARCOMA

- NATPARA causes an increase in the incidence of osteosarcoma in rats
- The increase in rats is dependent on NATPARA dose and treatment duration

*Report suspected adverse reactions to Shire at
1-855-NATPARA (1-855-628-7272) or to the FDA at
1-800-FDA-1088 or www.fda.gov/medwatch*



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NATPARA REMS Program Prescriber Training

Appropriate Patient Selection

- Due to the potential risk of osteosarcoma, NATPARA is only recommended for patients who cannot be well-controlled on calcium and active forms of vitamin D alone and for whom the potential benefits are considered to outweigh this potential risk.
- Avoid use of NATPARA in patients who are at increased risk for osteosarcoma, such as:
 - Patients with Paget's disease of bone or unexplained elevations of alkaline phosphatase
 - Pediatric and young adult patients with open epiphyses
 - Patients with hereditary disorders predisposed to osteosarcoma
 - Patients with a prior history of external beam or implant radiation therapy involving the skeleton



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NATPARA REMS Program Prescriber Training

NATPARA REMS Program Information

Program Overview

- Prescriber Certification
 - Certification consists of training, including successful completion of the Knowledge Assessment and enrolling in the NATPARA REMS Program
- Patient counseling on benefits and risks of NATPARA
- Completion of one-time NATPARA *REMS Program Patient-Prescriber Acknowledgment Form* – required before NATPARA can be dispensed from pharmacy
- Only certified pharmacies can dispense NATPARA



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NATPARA REMS Program Prescriber Training

NATPARA REMS Program

To become certified in the NATPARA REMS program, prescribers must complete the following steps:

1. Review the following:
 - NATPARA Prescribing Information
 - NATPARA REMS Program: An Introduction
 - NATPARA REMS Program Training Module for Prescribers
2. Successfully complete and submit the Knowledge Assessment at the end of this training module
3. Complete, sign, and submit the one-time NATPARA REMS Program Prescriber Enrollment Form



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NATPARA REMS Program Prescriber Training

Prescriber Certification and Enrollment Process

Prescriber certification and enrollment can be completed either online or through a paper-based process:

- 1) Online
 - Visit www.NATPARAREMS.com and click on the "Prescriber Certification" tab for online certification and enrollment instructions
- 2) Paper-based
 - Review the NATPARA Prescribing Information, NATPARA *REMS Program: An Introduction*, and the NATPARA *REMS Program Training Module for Prescribers*
 - Complete and submit both the Knowledge Assessment section from the NATPARA *REMS Program Training Module for Prescribers* and the NATPARA *REMS Program Prescriber Enrollment Form* to the NATPARA REMS Program Coordinating Center via:
 - Fax at 1-844-NAT-REMS (628-7367) or
 - Scan and email to NATPARAREMS@shire.com

REMS materials may be downloaded from the REMS website at www.NATPARAREMS.com; alternatively you may request hard copies by calling 1-855-NATPARA (628-7272)



I have reviewed the NATPARA *REMS Program Training Module for Prescribers*

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NATPARA REMS Program Prescriber Training

Patient Counseling on Benefit/Risk Profile

- Prescriber must counsel patients on the benefit/risk profile of NATPARA
 - The NATPARA *REMS Program Patient-Prescriber Acknowledgment Form* contains information on benefit and risks of NATPARA in patient-friendly language to counsel your patients
 - Provide patients with copies of the NATPARA *REMS Program Patient Brochure* and the NATPARA *REMS Program Patient-Prescriber Acknowledgment Form*



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I have reviewed the NATPARA *REMS Program Training Module for Prescribers*.

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NATPARA REMS Program Prescriber Training

Prescription Process

- Complete and sign the NATPARA *REMS Program Patient-Prescriber Acknowledgment Form* with each patient prior to initiation of therapy
- Provide patients with a copy of the signed form and a copy of the NATPARA *REMS Program Patient Brochure*
- Submit the NATPARA *REMS Program Patient-Prescriber Acknowledgment Form* and prescription for NATPARA to the NATPARA REMS Program Coordinating Center by fax at 1-844-NAT-REMS (628-7367) or scan and email to NATPARAREMS@shire.com
- The NATPARA REMS Program Coordinating Center will send the prescription to a certified pharmacy to fill after verifying that the prescriber is certified and a NATPARA *REMS Program Patient-Prescriber Acknowledgment Form* is on record
- Certified pharmacies will not dispense NATPARA if a prescriber is not certified and/or the NATPARA *REMS Program Patient-Prescriber Acknowledgment Form* is not on record
- The certified pharmacy will contact the patient to arrange the date to ship NATPARA once the prescription is filled



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NATPARA REMS Program Prescriber Training

Questions about the NATPARA REMS Program



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NATPARA REMS Program Prescriber Training

Questions about the NATPARA REMS Program

- Visit www.NATPARAREMS.com
- Call 1-855-NATPARA (628-7272)



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I have reviewed the NATPARA REMS Program Training Module for Prescribers

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NATPARA REMS Program Prescriber Training

Click the button below to open the NATPARA Prescribing Information.

Open NATPARA Prescribing Information

I have reviewed the NATPARA Prescribing Information

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NATPARA REMS Program Prescriber Training

Click the button below to open the NATPARA Prescribing Information.

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NATPARA REMS Program Prescriber Training

Click the links below to open and save the following training materials

[Download NATPARA REMS Program: An Introduction](#)

[Download NATPARA REMS Program Training Module for Prescribers](#)

[Download NATPARA Prescribing Information](#)

[Previous](#) [Next](#)

NATPARA REMS Program Prescriber Knowledge Assessment

You are about to begin the Knowledge Assessment. PLEASE READ important information:

- You will take a Knowledge Assessment consisting of **seven (7)** multiple choice and true or false questions.
- You will need to set aside at least **10 minutes** to complete the assessment.
- The session expires after **30 minutes** of inactivity; however, you may log back and continue where you left off.
- You must achieve a **passing score of 100%**.
- You will be allowed up to **three (3) attempts** to achieve the passing score.
- After three (3) incorrect responses you will be **locked out** and **deemed ineligible to prescribe**. You **will not** be able to return and complete the assessment.

START

Screenshot #27

Question 1 of the Knowledge Assessment



Introduction Training **Assessment** Enrollment Certificate

Question 1

NATPARA is only available through the NATPARA REMS Program

True

False

Submit

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Question 2

What is the approved indication statement for NATPARA?

- NATPARA is a parathyroid hormone replacement therapy indicated for the treatment of hypoparathyroidism
- NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism
- NATPARA is indicated as monotherapy for hypoparathyroidism
- NATPARA is indicated as monotherapy for hypocalcemia

Submit

Question 3

NATPARA causes an increase in the incidence of osteosarcoma in rats

- True
- False

Submit

Question 4

Avoid use of NATPARA in patients who are at increased risk of osteosarcoma, such as:

- Patients with Paget's disease of bone or unexplained elevations in alkaline phosphatase
- Pediatric and young adult patients with open epiphyses
- Patients with hereditary disorders predisposed to osteosarcoma
- Patients with a prior history of external beam or implant radiation therapy involving the skeleton
- All of the above

Submit

Question 5

How often should the NATPARA REMS Program Patient-Prescriber Acknowledgment Form be completed?

- With each new prescription
- With every refill
- Once a year
- One-time for each new patient

Submit

Question 6

Patients who are controlled on a regimen of calcium and vitamin D should be switched to NATPARA

- True
- False

Submit

Question 7

Prescribers must counsel patients on the risk/benefit profile for NATPARA

- True
- False

Submit

NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #29

Question 1 of the Knowledge Assessment answered correctly

Natpara
(parathyroid hormone)
for injection
24 • 36 • 72 • 90 mcg per 0.5 mL strength

Introduction Training **Assessment** Enrollment Certificate

Question 1

NATPARA is only available through the NATPARA REMS Program

True
 False

Your answer is correct.

NATPARA is available only through a restricted program called the NATPARA REMS Program. Prescribers must become certified in the NATPARA REMS Program to be able to prescribe NATPARA. Pharmacies must be certified to dispense NATPARA. NATPARA must be dispensed only to patients informed about the potential risk of osteosarcoma associated with the use of NATPARA.

[Next](#)

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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #30

Question 2 of the Knowledge Assessment

Natpara
(parathyroid hormone)
for injection
20 • 30 • 75 • 90mg per dose strength

Introduction Training **Assessment** Enrollment Certify

Question 2

What is the approved indication statement for NATPARA?

- NATPARA is a parathyroid hormone replacement therapy indicated for the treatment of hypoparathyroidism
- NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism
- NATPARA is indicated as monotherapy for hypoparathyroidism
- NATPARA is indicated as monotherapy for hypocalcemia

Submit

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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #31

Question 2 of the Knowledge Assessment answered incorrectly; the number of remaining attempts is displayed; users must click “Review Training” prior to being able to answer the question again.

Natpara
(parathyroid hormone)
for injection
24 • 36 • 75 • 100 mcg per dose strength

Introduction Training **Assessment** Enrollment Certify

Question 2

What is the approved indication statement for NATPARA?

- NATPARA is a parathyroid hormone replacement therapy indicated for the treatment of hypoparathyroidism
- NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism
- NATPARA is indicated as monotherapy for hypoparathyroidism
- NATPARA is indicated as monotherapy for hypocalcemia

Your answer is incorrect.

This is your first incorrect answer. You have two attempts remaining. Click on "Review Training" to review the corresponding training material prior to answering the question again.

Review Training

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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #32

Upon clicking “Review Training” the user is led to the slide(s) corresponding to the incorrectly answered question; the user must click the box “I have reviewed the slide(s) in order to return to the question.

The screenshot shows a training slide for NATPARA. At the top left is the Natpara logo with the text "(parathyroid hormone) for Injection" and "20 • 30 • 50 • 90 mg per 0.5 mL strength". At the top right is a navigation bar with buttons for "Introduction", "Training" (which is highlighted), "Assessment", "Enrollment", and "Certificate". Below the navigation bar is a purple header with the text "NATPARA REMS Program Prescriber Training". The main content area features a slide titled "Indication" with a decorative graphic of four overlapping circles in blue, red, and purple. The slide text reads: "NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism." followed by a bulleted list: "• NATPARA is not a parathyroid hormone replacement" and "– Limitations of Use:" with three sub-bullets: "• Because of the potential risk of osteosarcoma, NATPARA is recommended only for patients who cannot be well-controlled on calcium and active forms of vitamin D alone", "• NATPARA was not studied in patients with hypoparathyroidism caused by calcium sensing receptor mutations", and "• NATPARA was not studied in patients with acute post-surgical hypoparathyroidism". The Natpara logo is repeated in the bottom right corner of the slide. At the bottom left of the slide, there is a checkbox labeled "I have reviewed the slide(s)". At the bottom right, there is a blue button labeled "Return to Question". The footer of the slide contains "Privacy Policy" and "Terms of Use" on the left, and "© 2016 All rights reserved. This site is intended for U.S. residents only. NAT-019-0115 Version 1.1" on the right.

NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #33

Second attempt at answering Question 2 of the Knowledge Assessment

Natpara
(parathyroid hormone)
for injection
200 IU/30 mL (300 USP units/mL)

Introduction Training **Assessment** Enrollment Certify

Question 2

What is the approved indication statement for NATPARA?

- NATPARA is a parathyroid hormone replacement therapy indicated for the treatment of hypoparathyroidism
- NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism
- NATPARA is indicated as monotherapy for hypoparathyroidism
- NATPARA is indicated as monotherapy for hypocalcemia

Submit

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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #34

Question 2 of the Knowledge Assessment answered correctly

Natpara
(parathyroid hormone)
for injection
20 • 30 • 40 mg per 0.5 mL strength

Introduction Training **Assessment** Enrollment Certificate

Question 2

What is the approved indication statement for NATPARA?

- NATPARA is a parathyroid hormone replacement therapy indicated for the treatment of hypoparathyroidism
- NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism
- NATPARA is indicated as monotherapy for hypoparathyroidism
- NATPARA is indicated as monotherapy for hypocalcemia

Your answer is correct.

NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.

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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #35

Question 3 of the Knowledge Assessment

Natpara
(parathyroid hormone)
for injection

Introduction Training **Assessment** Enrollment Certificate

Question 3

NATPARA causes an increase in the incidence of osteosarcoma in rats

True

False

Submit

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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #36

Question 3 of the Knowledge Assessment answered correctly

Natpara
(parathyroid hormone)
for injection
20-40 IU (10-100 mg) parathyroid strength

Introduction Training **Assessment** Enrollment Certify

Question 3

NATPARA causes an increase in the incidence of osteosarcoma in rats

True
 False

Your answer is correct.

NATPARA causes an increase in the incidence of osteosarcoma in rats. The increase in rats is dependent on NATPARA dose and treatment duration.

Next

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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #37

Question 4 of the Knowledge Assessment

Natpara
(parathyroid hormone)
for injection
20 • 30 • 40 • 60 mg parathyroid hormone

Introduction Training **Assessment** Enrollment Certificate

Question 4

Avoid use of NATPARA in patients who are at increased risk of osteosarcoma, such as:

- Patients with Paget's disease of bone or unexplained elevations in alkaline phosphatase
- Pediatric and young adult patients with open epiphyses
- Patients with hereditary disorders predisposed to osteosarcoma
- Patients with a prior history or external beam or implant radiation therapy involving the skeleton
- All of the above

Submit

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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #38

Question 4 of the Knowledge Assessment answered correctly



Introduction Training **Assessment** Enrollment Certificate

Question 4

Avoid use of NATPARA in patients who are at increased risk of osteosarcoma, such as:

- Patients with Paget's disease of bone or unexplained elevations in alkaline phosphatase
- Pediatric and young adult patients with open epiphyses
- Patients with hereditary disorders predisposed to osteosarcoma
- Patients with a prior history of external beam or implant radiation therapy involving the skeleton
- All of the above

Your answer is correct.

Avoid use of NATPARA in patients who are at increased risk of osteosarcoma, such as: patients with Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, patients with hereditary disorders predisposed to osteosarcoma, patients with a prior history of external beam or implant radiation therapy involving the skeleton.

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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #39

Question 5 of the Knowledge Assessment

Natpara
(parathyroid hormone)
for injection
20-50 IU/30mL suspension strength

Introduction Training **Assessment** Enrollment Certify

Question 5

How often should the NATPARA REMS Program Patient-Prescriber Acknowledgment Form be completed?

- With each new prescription
- With every refill
- Once a year
- One-time for each new patient

Submit

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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #40

Question 5 of the Knowledge Assessment answered correctly

Natpara
(parathyroid hormone)
for injection
20 • 30 • 40 mg/0.5 mL (30 mg/0.5 mL)

Introduction Training **Assessment** Enrollment Certify

Question 5

How often should the NATPARA REMS Program Patient-Prescriber Acknowledgment Form be completed?

- With each new prescription
- With every refill
- Once a year
- One-time for each new patient

Your answer is correct.

The NATPARA REMS Program Patient-Prescriber Acknowledgment Form should be completed one-time for each new patient and is required before NATPARA can be dispensed from pharmacy.

Next

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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #41

Question 6 of the Knowledge Assessment

Natpara
(parathyroid hormone)
for injection
30 • 30 • 75 • 150mcg per dose strength

Introduction Training **Assessment** Enrollment Certificate

Question 6

Patients who are controlled on a regimen of calcium and vitamin D should be switched to NATPARA

True

False

Submit

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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #42

Question 6 of the Knowledge Assessment answered correctly

Natpara
(parathyroid hormone)
for injection
30 • 50 • 75 • 100 mg per dose strength

Introduction Training **Assessment** Enrollment Certify

Question 6

Patients who are controlled on a regimen of calcium and vitamin D should be switched to NATPARA

True

False

Your answer is correct.

NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism. NATPARA is not a parathyroid hormone replacement. Limitations of Use:

- Because of the potential risk of osteosarcoma, NATPARA is recommended only for patients who cannot be well-controlled on calcium and active forms of vitamin D alone
- NATPARA was not studied in patients with hypoparathyroidism caused by calcium sensing receptor mutations
- NATPARA was not studied in patients with acute post-surgical hypoparathyroidism

Next

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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #43

Question 7 of the Knowledge Assessment

The screenshot displays the NATPARA REMS program interface. At the top left is the logo for Natpara (parathyroid hormone) for injection, 20-30 IU/30mL injection. To the right of the logo is a progress bar with five steps: Introduction, Training, Assessment, Enrollment, and Certify. The 'Assessment' step is currently active. Below the progress bar is a dark blue header with the text 'Question 7'. The main content area contains the question text: 'Prescribers must counsel patients on the risk/benefit profile for NATPARA'. Below the question are two radio button options: 'True' and 'False'. A 'Submit' button is centered below the options. At the bottom left of the page are links for 'Privacy Policy' and 'Terms of Use'. At the bottom right is the copyright notice: '© 2016 All rights reserved. This site is intended for U.S. residents only. NAT-019-0115 Version 1.1'.

Natpara
(parathyroid hormone)
for injection
20-30 IU/30mL injection

Introduction Training **Assessment** Enrollment Certify

Question 7

Prescribers must counsel patients on the risk/benefit profile for NATPARA

True

False

Submit

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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #44

Question 7 of the Knowledge Assessment answered correctly

Natpara
(parathyroid hormone)
for Injection
20 • 30 • 70 • 100mcg/0.5mL strength

Introduction Training **Assessment** Enrollment Certify

Question 7

Prescribers must counsel patients on the risk/benefit profile for NATPARA

True
 False

Your answer is correct.

Prescribers must counsel patients on the benefit/risk profile of NATPARA. The NATPARA REMS Program Patient-Prescriber Acknowledgment Form contains information on benefit and risks of NATPARA in patient-friendly language to counsel your patients. Prescribers should provide patients with copies of the NATPARA REMS Program Patient Brochure and the NATPARA REMS Program Patient-Prescriber Acknowledgment.

Next

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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Additional screenshots

Screenshot #52

Question 1 answered incorrectly (in this example it is a user's first incorrect attempt).

Natpara
(parathyroid hormone)
for injection
24 • 36 • 75 • 100mg per dose strength

Introduction Training **Assessment** Enrollment Certicate

Question 1

NATPARA is only available through the NATPARA REMS Program

True

False

Your answer is incorrect.

This is your first incorrect answer. You have two attempts remaining. Click on "Review Training" to review the corresponding training material prior to answering the question again.

[Review Training](#)

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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #53

Corresponding slide a user must review when Question 1 is answered incorrectly, prior to answering the question again.

The screenshot displays the NATPARA REMS Program Prescriber Training interface. At the top left, the Natpara logo is shown with the text "(parathyroid hormone) for injection" and "20-30 mg/30 min suspension through". At the top right, a progress bar indicates the current slide is "Introduction", with other stages "Assessment", "Enrollment", and "Certificate" also visible. The main content area features a slide titled "Introduction" with a decorative graphic on the right. The slide text reads:

- NATPARA is available only through a restricted program called the NATPARA REMS (Risk Evaluation and Mitigation Strategy) Program
 - Prescribers must become certified in the NATPARA REMS Program to be able to prescribe NATPARA
 - Pharmacies must be certified to dispense NATPARA
 - NATPARA must be dispensed only to patients informed about the potential risk of osteosarcoma associated with the use of NATPARA

At the bottom left of the slide area, there is a checkbox labeled "I have reviewed the slide(s)". At the bottom right, there is a "Return to Question" button. The footer contains "Privacy Policy" and "Terms of Use" on the left, and "© 2016 All rights reserved. This site is intended for U.S. residents only. NAT-019-0115 Version 1.1" on the right.

NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #54

Question 3 answered incorrectly (in this example it is a user's first incorrect attempt).

The screenshot displays the Natpara (parathyroid hormone) for Injection assessment interface. At the top, the Natpara logo and product information are visible. A progress bar shows the user is currently in the 'Assessment' phase, with 'Introduction', 'Training', 'Enrollment', and 'Certificate' phases also indicated. The main content area is titled 'Question 3' and contains the following text: 'NATPARA causes an increase in the incidence of osteosarcoma in rats'. Below this, there are two radio button options: 'True' and 'False'. The 'False' option is selected. A red message states: 'Your answer is incorrect. This is your second incorrect answer. You have one attempt remaining. Click on "Review Training" to review the corresponding training material prior to answering the question again.' A blue 'Review Training' button is centered below the message. At the bottom of the screen, there are links for 'Privacy Policy' and 'Terms of Use', and a copyright notice: '© 2016 All rights reserved. This site is intended for U.S. residents only. NAT-019-0115 Version 1.1'.

Natpara
(parathyroid hormone)
for Injection
20 • 30 • 50 • 100 mg per dose strength

Introduction Training **Assessment** Enrollment Certificate

Question 3

NATPARA causes an increase in the incidence of osteosarcoma in rats

True

False

Your answer is incorrect.

This is your second incorrect answer. You have one attempt remaining.
Click on "Review Training" to review the corresponding training material prior to answering the question again.

[Review Training](#)

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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #55

Corresponding slide (1 of 2) a user must review when Question 3 is answered incorrectly, prior to answering the question again.

The screenshot displays a training slide titled "Boxed Warning" for Natpara (parathyroid hormone) for injection. The slide content includes:

- Boxed Warning:**
 - WARNING: POTENTIAL RISK OF OSTEOSARCOMA**
 - NATPARA causes an increase in the incidence of osteosarcoma in rats
 - The increase in rats is dependent on NATPARA dose and treatment duration
- Report suspected adverse reactions to Shire at 1-855-NATPARA (1-855-628-7272) or to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Navigation elements include "Previous Slide" and "Next Slide" buttons. A "Return to Question" button is located at the bottom right. A status bar at the bottom left shows "I have reviewed the slide(s)". The footer contains "Privacy Policy", "Terms of Use", and "© 2016 All rights reserved. This site is intended for U.S. residents only. NAT-019-0115 Version 1.1".

NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #56

Corresponding slide (2 of 2) a user must review when Question 3 is answered incorrectly, prior to answering the question again.

The screenshot shows a web-based training interface for the NATPARA REMS Program. At the top left is the Natpara logo (parathyroid hormone) for injection, 50 mcg/0.5 mL (100 mcg per 0.5 mL vial). At the top right is a progress bar with five steps: Introduction, Training (active), Assessment, Enrollment, and Certify. Below the progress bar is a dark blue header with the text 'NATPARA REMS Program Prescriber Training'. The main content area features a slide titled 'Appropriate Patient Selection' with a decorative graphic on the right. The slide text reads: 'Due to the potential risk of osteosarcoma, NATPARA is only recommended for patients who cannot be well-controlled on calcium and active forms of vitamin D alone and for whom the potential benefits are considered to outweigh this potential risk.' and 'Avoid use of NATPARA in patients who are at increased risk for osteosarcoma, such as:'. The list of contraindications includes: 'Patients with Paget's disease of bone or unexplained elevations of alkaline phosphatase', 'Pediatric and young adult patients with open epiphyses', 'Patients with hereditary disorders predisposed to osteosarcoma', and 'Patients with a prior history of external beam or implant radiation therapy involving the skeleton'. The slide also includes the Natpara logo and the number '8'. Navigation buttons for 'Previous Slide' and 'Next Slide' are on the left and right sides of the slide. At the bottom left of the slide area is a checkbox labeled 'I have reviewed the slide(s)'. At the bottom right is a 'Return to Question' button. The footer contains 'Privacy Policy Terms of Use' on the left and '© 2016 All rights reserved. This site is intended for U.S. residents only. NAT-019-0115 Version 1.1' on the right.

Natpara
(parathyroid hormone)
for injection
50 mcg/0.5 mL (100 mcg per 0.5 mL vial)

Introduction **Training** Assessment Enrollment Certify

NATPARA REMS Program Prescriber Training

Appropriate Patient Selection

- Due to the potential risk of osteosarcoma, NATPARA is only recommended for patients who cannot be well-controlled on calcium and active forms of vitamin D alone and for whom the potential benefits are considered to outweigh this potential risk.
- Avoid use of NATPARA in patients who are at increased risk for osteosarcoma, such as:
 - Patients with Paget's disease of bone or unexplained elevations of alkaline phosphatase
 - Pediatric and young adult patients with open epiphyses
 - Patients with hereditary disorders predisposed to osteosarcoma
 - Patients with a prior history of external beam or implant radiation therapy involving the skeleton

I have reviewed the slide(s)

[Return to Question](#)

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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #57

Question 4 answered incorrectly (in this example it is a user's second incorrect attempt).

The screenshot displays the Natpara REMS program interface. At the top left is the Natpara logo with the text "parathyroid hormone for injection" and "24-36-75-150 mg per 0.9 mL strength". At the top right is a progress bar with five stages: Introduction, Training, Assessment (highlighted), Enrollment, and Certify. Below the progress bar is a dark blue header with the text "Question 4". The main content area contains the following text: "Avoid use of NATPARA in patients who are at increased risk of osteosarcoma, such as:". Below this is a list of five radio button options: "Patients with Paget's disease of bone or unexplained elevations in alkaline phosphatase", "Pediatric and young adult patients with open epiphyses", "Patients with hereditary disorders predisposed to osteosarcoma", "Patients with a prior history or external beam or implant radiation therapy involving the skeleton" (which is selected), and "All of the above". Below the options, a red message states: "Your answer is incorrect." followed by: "This is your first incorrect answer. You have two attempts remaining. Click on 'Review Training' to review the corresponding training material prior to answering the question again." A blue button labeled "Review Training" is centered below the message. At the bottom left, there are links for "Privacy Policy" and "Terms of Use". At the bottom right, the copyright notice reads: "© 2016 All rights reserved. This site is intended for U.S. residents only. NAT-019-0115 Version 1.1".

NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #58

Corresponding slide a user must review when Question 4 is answered incorrectly, prior to answering the question again.

The screenshot displays the NATPARA REMS Program Prescriber Training interface. At the top left is the Natpara logo (parathyroid hormone) for injection, 20-40 IU (10-20 mg) per dose strength. At the top right are navigation tabs: Introduction, Training (selected), Assessment, Enrollment, and Certicate. Below the navigation is a purple header bar with the text "NATPARA REMS Program Prescriber Training". The main content area features a slide titled "Appropriate Patient Selection" with a decorative graphic on the right. The slide text reads:

- Due to the potential risk of osteosarcoma, NATPARA is only recommended for patients who cannot be well-controlled on calcium and active forms of vitamin D alone and for whom the potential benefits are considered to outweigh this potential risk.
- Avoid use of NATPARA in patients who are at increased risk for osteosarcoma, such as:
 - Patients with Paget's disease of bone or unexplained elevations of alkaline phosphatase
 - Pediatric and young adult patients with open epiphyses
 - Patients with hereditary disorders predisposed to osteosarcoma
 - Patients with a prior history of external beam or implant radiation therapy involving the skeleton

At the bottom left of the slide area is a checkbox labeled "I have reviewed the slide(s)". At the bottom right is a "Return to Question" button. The footer contains "Privacy Policy" and "Terms of Use" on the left, and "© 2016 All rights reserved. This site is intended for U.S. residents only. NAT-019-0115 Version 1.1" on the right.

NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #59

Question 5 answered incorrectly (in this example it is a user's first incorrect attempt).

Natpara
(parathyroid hormone)
for injection
20 • 30 • 40 • 60 mg single dose syringe

Introduction Training **Assessment** Enrollment Certify

Question 5

How often should the NATPARA REMS Program Patient-Prescriber Acknowledgment Form be completed?

- With each new prescription
- With every refill
- Once a year
- One-time for each new patient

Your answer is incorrect.

This is your first incorrect answer. You have two attempts remaining. Click on "Review Training" to review the corresponding training material prior to answering the question again.

[Review Training](#)

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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #60

Corresponding slide (1 of 2) a user must review when Question 5 is answered incorrectly, prior to answering the question again.

The screenshot displays a web-based training interface for the NATPARA REMS Program. At the top, a navigation bar includes the Natpara logo (parathyroid hormone for injection) and a progress indicator with five steps: Introduction, Training (highlighted), Assessment, Enrollment, and Certicate. Below the navigation bar is a dark blue header with the text "NATPARA REMS Program Prescriber Training". The main content area features a central slide titled "NATPARA REMS Program Information" with a decorative graphic on the right. The slide content includes a "Program Overview" section with a bulleted list: "Prescriber Certification" (with a sub-bullet: "Certification consists of training, including successful completion of the Knowledge Assessment and enrolling in the NATPARA REMS Program"), "Patient counseling on benefits and risks of NATPARA", "Completion of one-time NATPARA REMS Program Patient-Prescriber Acknowledgment Form – required before NATPARA can be dispensed from pharmacy", and "Only certified pharmacies can dispense NATPARA". Navigation controls include "Previous Slide" and "Next Slide" buttons. At the bottom of the slide, there is a "Return to Question" button and a checkbox labeled "I have reviewed the slide(s)". The footer contains "Privacy Policy" and "Terms of Use" links on the left, and a copyright notice "© 2016 All rights reserved. This site is intended for U.S. residents only. NAT-019-0115 Version 1.1" on the right.

NATPARA REMS Program Information

Program Overview

- Prescriber Certification
 - Certification consists of training, including successful completion of the Knowledge Assessment and enrolling in the NATPARA REMS Program
- Patient counseling on benefits and risks of NATPARA
- Completion of one-time NATPARA *REMS Program Patient-Prescriber Acknowledgment Form* – required before NATPARA can be dispensed from pharmacy
- Only certified pharmacies can dispense NATPARA

I have reviewed the slide(s)

[Return to Question](#)

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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #61

Corresponding slide (2 of 2) a user must review when Question 5 is answered incorrectly, prior to answering the question again.

The screenshot shows a web-based training interface for the NATPARA REMS Program. At the top left is the Natpara logo (parathyroid hormone for injection, 20-50, 75, 100mcg/0.5ml vial) and a progress bar with five steps: Introduction, Training (active), Assessment, Enrollment, and Certify. Below the progress bar is a dark blue header with the text "NATPARA REMS Program Prescriber Training". The main content area features a slide titled "NATPARA REMS Program" with a blue and red logo. The slide text reads: "To become certified in the NATPARA REMS program, prescribers must complete the following steps:" followed by a numbered list: 1. Review the following: - NATPARA Prescribing Information - NATPARA REMS Program: An Introduction - NATPARA REMS Program Training Module for Prescribers; 2. Successfully complete and submit the Knowledge Assessment at the end of this training module; 3. Complete, sign, and submit the one-time NATPARA REMS Program Prescriber Enrollment Form. The slide includes "Previous Slide" and "Next Slide" navigation buttons. At the bottom left of the slide is a checkbox labeled "I have reviewed the slide(s)". At the bottom right of the slide is a "Return to Question" button. The footer of the interface includes "Privacy Policy" and "Terms of Use" on the left, and "© 2016 All rights reserved. This site is intended for U.S. residents only. NAT-019-0115 Version 1.1" on the right.

NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #62

Question 6 answered incorrectly (in this example it is a user's second incorrect attempt).

The screenshot displays the NATPARA (parathyroid hormone) for injection logo in the top left corner. A progress bar at the top right shows five steps: Introduction, Training, Assessment (highlighted), Enrollment, and Certify. The main content area is titled "Question 6" and contains the following text: "Patients who are controlled on a regimen of calcium and vitamin D should be switched to NATPARA". Below this, there are two radio button options: "True" (selected) and "False". A red message states: "Your answer is incorrect. This is your second incorrect answer. You have one attempt remaining. Click on 'Review Training' to review the corresponding training material prior to answering the question again." A blue "Review Training" button is centered below the message. At the bottom left, there are links for "Privacy Policy" and "Terms of Use". At the bottom right, the copyright notice reads: "© 2016 All rights reserved. This site is intended for U.S. residents only. NAT-019-0115 Version 1.1".

NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #63

Corresponding slide (1 of 2) a user must review when Question 6 is answered incorrectly, prior answering the question again.

The screenshot shows a slide from the NATPARA REMS Program Prescriber Training. The slide is titled "Indication" and contains the following text:

NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.

- NATPARA is not a parathyroid hormone replacement
 - Limitations of Use:
 - Because of the potential risk of osteosarcoma, NATPARA is recommended only for patients who cannot be well-controlled on calcium and active forms of vitamin D alone
 - NATPARA was not studied in patients with hypoparathyroidism caused by calcium sensing receptor mutations
 - NATPARA was not studied in patients with acute post-surgical hypoparathyroidism

The slide also features the Natpara logo in the top left and bottom right corners. Navigation buttons for "Previous Slide" and "Next Slide" are visible on the left and right sides of the slide content area. A "Return to Question" button is located at the bottom right of the slide. A red text prompt "I have reviewed the slide(s)" is visible at the bottom left of the slide area. The top navigation bar includes "Introduction", "Training", "Assessment", "Enrollment", and "Certificate". The bottom footer contains "Privacy Policy", "Terms of Use", and "© 2016 All rights reserved. This site is intended for U.S. residents only. NAT-019-0115 Version 1.1".

NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #64

Corresponding slide (2 of 2) a user must review when Question 6 is answered incorrectly, prior to answering the question again.

The screenshot shows a web-based training interface for the NATPARA REMS Program. At the top, there is a navigation bar with the Natpara logo (parathyroid hormone for injection, 20-50 IU/10mL) and a progress indicator. The progress bar shows five steps: Introduction, Training (current), Assessment, Enrollment, and Certify. Below the navigation bar is a dark blue header with the text "NATPARA REMS Program Prescriber Training".

The main content area displays a slide titled "Appropriate Patient Selection". The slide contains the following text and list:

- Due to the potential risk of osteosarcoma, NATPARA is only recommended for patients who cannot be well-controlled on calcium and active forms of vitamin D alone and for whom the potential benefits are considered to outweigh this potential risk.
- Avoid use of NATPARA in patients who are at increased risk for osteosarcoma, such as:
 - Patients with Paget's disease of bone or unexplained elevations of alkaline phosphatase
 - Pediatric and young adult patients with open epiphyses
 - Patients with hereditary disorders predisposed to osteosarcoma
 - Patients with a prior history of external beam or implant radiation therapy involving the skeleton

Navigation controls include a "Previous Slide" button on the left and a "Next Slide" button on the right. At the bottom of the slide, there is a checkbox labeled "I have reviewed the slide(s)" and a "Return to Question" button. The footer of the slide includes the Natpara logo and the text "© 2016 All rights reserved. This site is intended for U.S. residents only. NAT-019-0115 Version 1.1".

NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #65

Question 7 answered incorrectly (in this example it is a user's second incorrect attempt).

The screenshot displays the Natpara (parathyroid hormone) for Injection assessment interface. At the top, the Natpara logo and product information are visible on the left, and a progress bar with five steps (Introduction, Training, Assessment, Enrollment, Certify) is on the right. The 'Assessment' step is currently active. Below the progress bar, the title 'Question 7' is displayed in a dark blue header. The main content area contains the question: 'Prescribers must counsel patients on the risk/benefit profile for NATPARA'. Two radio button options are provided: 'True' and 'False'. The 'False' option is selected, and a red message indicates 'Your answer is incorrect.' Below this, a red message states: 'This is your first incorrect answer. You have two attempts remaining. Click on "Review Training" to review the corresponding training material prior to answering the question again.' A blue button labeled 'Review Training' is centered below the message. At the bottom of the screen, there are links for 'Privacy Policy' and 'Terms of Use' on the left, and a copyright notice '© 2016 All rights reserved. This site is intended for U.S. residents only. NAT-019-0115 Version 1.1' on the right.

NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #66

Corresponding slide a user must review when Question 7 is answered incorrectly, prior to answering the question again

The screenshot displays the NATPARA REMS Program Prescriber Training interface. At the top left is the Natpara logo (parathyroid hormone) for injection. A progress bar at the top right shows five steps: Introduction, Training (active), Assessment, Enrollment, and Certify. The main content area features a slide titled "Patient Counseling on Benefit/Risk Profile" with a decorative graphic on the right. The slide lists two bullet points: "Prescriber must counsel patients on the benefit/risk profile of NATPARA" and "The NATPARA REMS Program Patient-Prescriber Acknowledgment Form contains information on benefit and risks of NATPARA in patient-friendly language to counsel your patients". A second bullet point states: "Provide patients with copies of the NATPARA REMS Program Patient Brochure and the NATPARA REMS Program Patient-Prescriber Acknowledgment Form". The Natpara logo and the number "13" are at the bottom right of the slide. Below the slide, there is a checkbox labeled "I have reviewed the slide(s)" and a "Return to Question" button. The footer contains "Privacy Policy Terms of Use" and "© 2016 All rights reserved. This site is intended for U.S. residents only. NAT-019-0115 Version 1.1".

Natpara
(parathyroid hormone)
for injection

Introduction Training Assessment Enrollment Certify

NATPARA REMS Program Prescriber Training

Patient Counseling on Benefit/Risk Profile

- Prescriber must counsel patients on the benefit/risk profile of NATPARA
 - The NATPARA REMS Program Patient-Prescriber Acknowledgment Form contains information on benefit and risks of NATPARA in patient-friendly language to counsel your patients
 - Provide patients with copies of the NATPARA REMS Program Patient Brochure and the NATPARA REMS Program Patient-Prescriber Acknowledgment Form

I have reviewed the slide(s)

[Return to Question](#)

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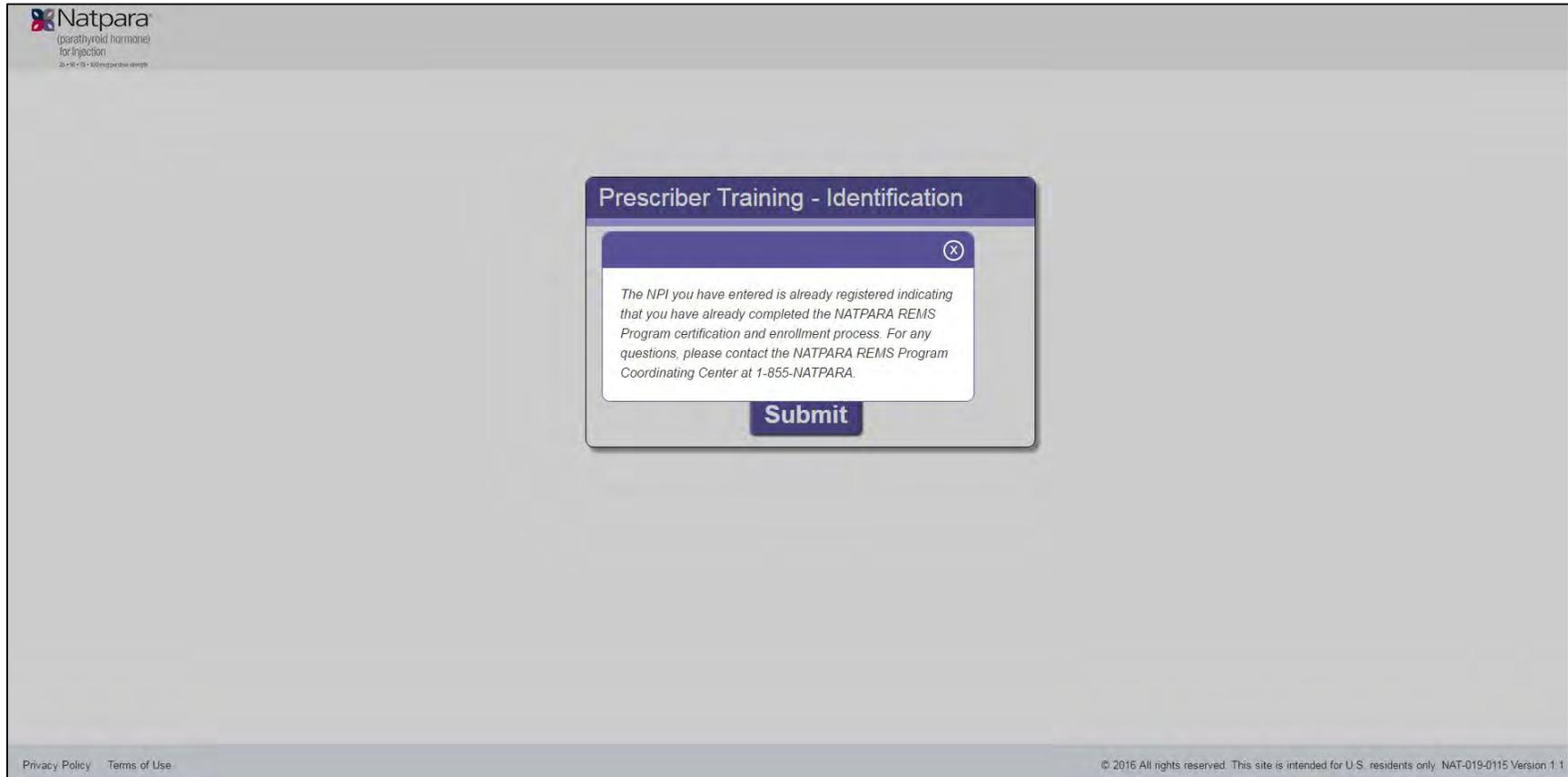
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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #67

Pop-up message to an HCP who already completed the certification and enrollment process:

The NPI you have entered is already registered indicating that you have already completed the NATPARA REMS Program certification and enrollment process. For any questions, please contact the NATPARA REMS Program Coordinating Center at 1-855-NATPARA.

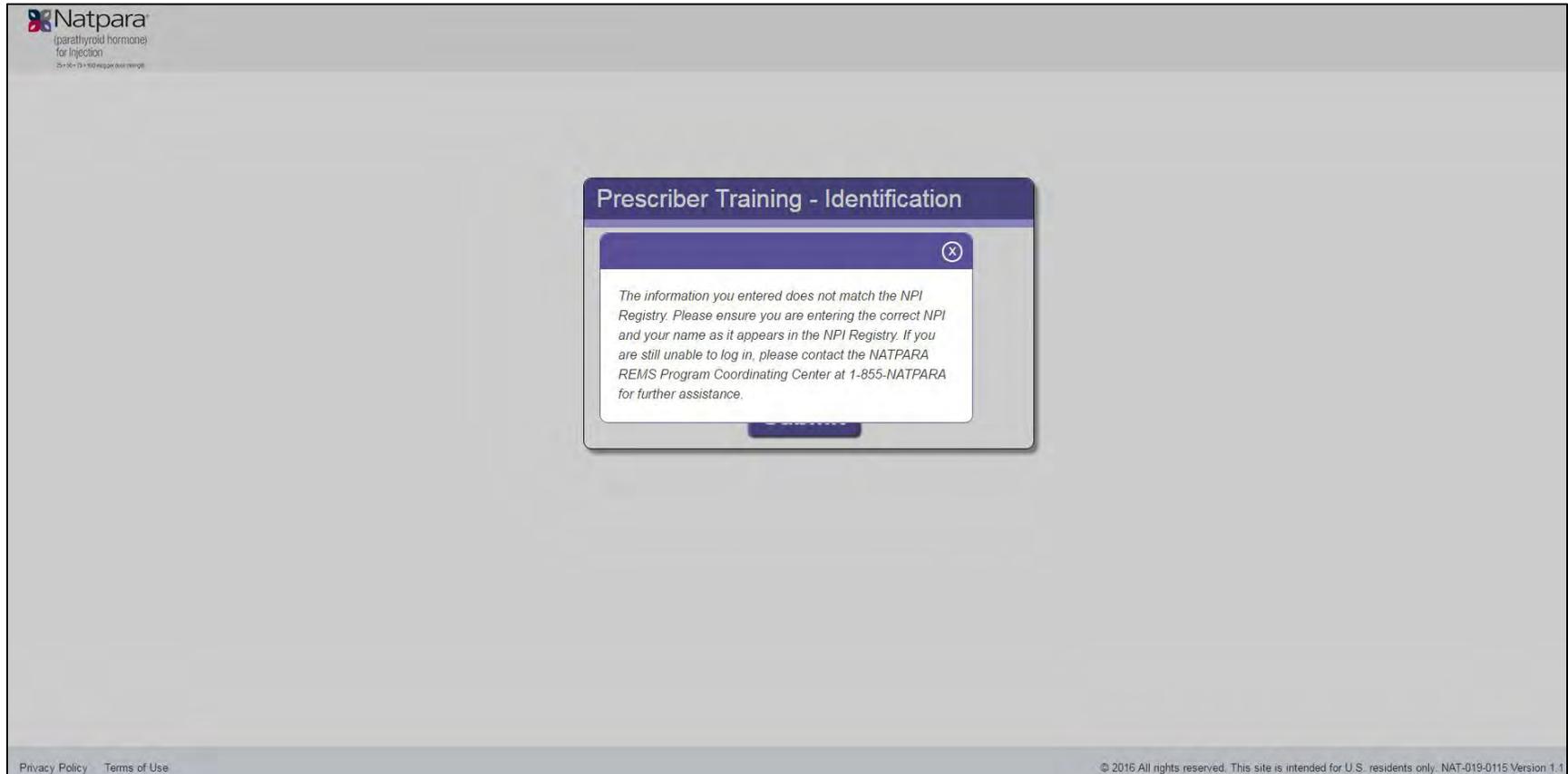


NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #68

Pop-up message to an HCP entering incorrect NPI/name:

The information you entered does not match the NPI Registry. Please ensure you are entering the correct NPI and your name as it appears in the NPI Registry. If you are still unable to log in, please contact the NATPARA REMS Program Coordinating Center at 1-855-NATPARA for further assistance.



NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #69

Pop-up message to an HCP who exceeded the number of incorrect attempts:

Your session has ended as you have exceeded the number of incorrect attempts. Please contact the NATPARA REMS Program Coordinating Center at 1-855-NATPARA to discuss the reasons for the incorrect attempts and the steps to take in order to complete the certification.

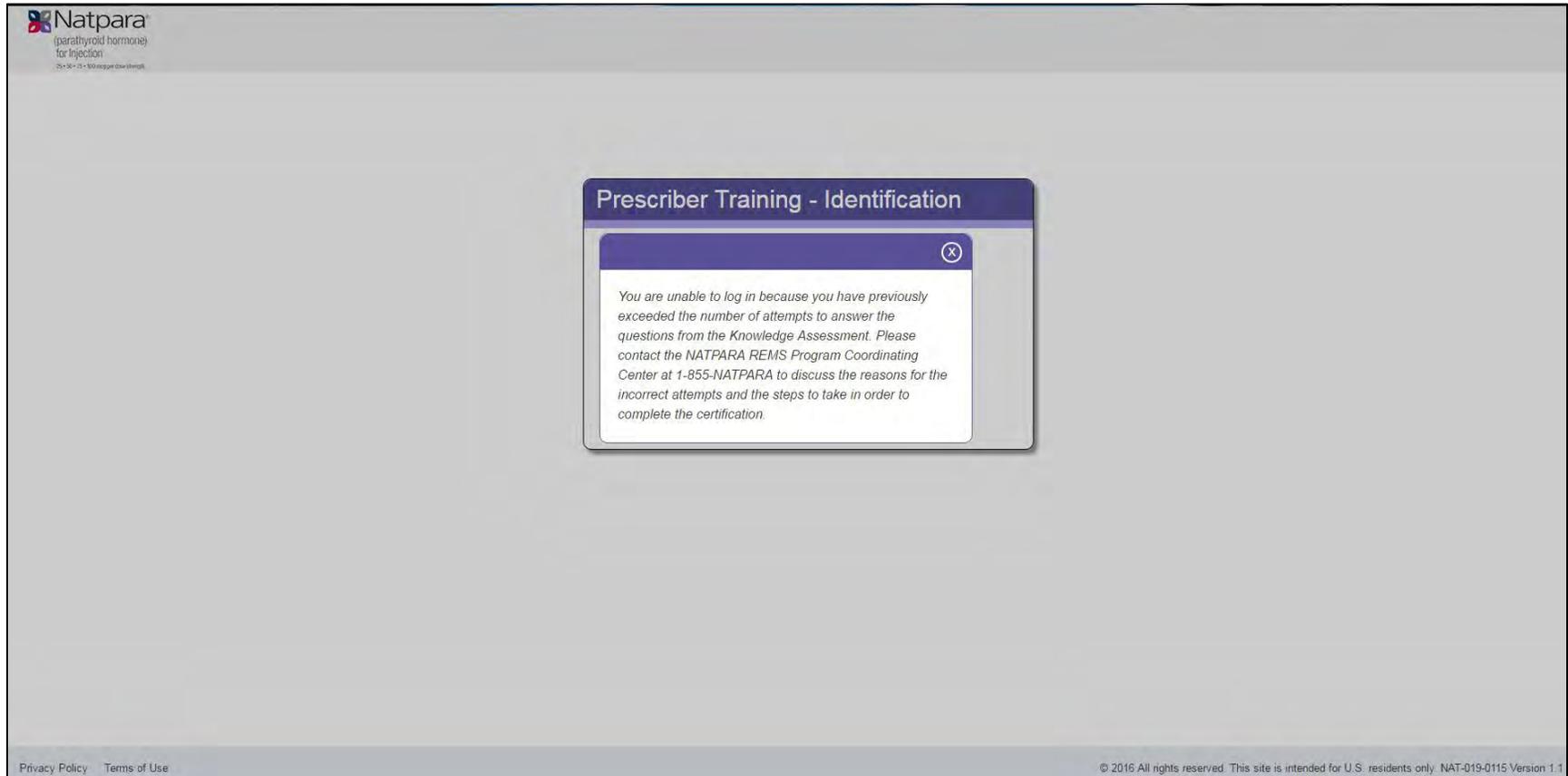
The screenshot displays the NATPARA REMS Program online prescriber certification interface. At the top left, the Natpara logo is visible, including the text "Natpara (parathyroid hormone) for injection" and "21-KG-15-30mgparhormone". A progress bar at the top right shows five stages: Introduction, Training, Assessment, Enrollment, and Certify, with the Assessment stage currently active. Below the progress bar, the text "Question 3" is displayed. The question text reads: "NATPARA causes an increase in the incidence of osteosarcoma in rats". Two radio button options are provided: "True" and "False", with "False" selected. A pop-up message titled "Exceeded Attempts" is overlaid on the question, containing the text: "Your session has ended as you have exceeded the number of incorrect attempts. Please contact the NATPARA REMS Program Coordinating Center at 1-855-NATPARA to discuss the reasons for the incorrect attempts and the steps to take in order to complete the certification." At the bottom left, there are links for "Privacy Policy" and "Terms of Use". At the bottom right, the copyright notice reads: "© 2016 All rights reserved. This site is intended for U.S. residents only. NAT-019-0115 Version 1.1".

NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #70

Pop-up message to an HCP who is ineligible to enroll (i.e., has failed the Knowledge Assessment either online or paper-based):

You are unable to log in because you have previously exceeded the number of attempts to answer the questions from the Knowledge Assessment. Please contact the NATPARA REMS Program Coordinating Center at 1-855-NATPARA to discuss the reasons for the incorrect attempts and the steps to take in order to complete the certification.



Conclusion

Thank you for completing the NATPARA REMS Program Prescriber Knowledge Assessment.

To become certified to prescribe NATPARA, you will need to complete and sign the NATPARA *REMS Program Prescriber Enrollment Form*.

[Enroll Now](#)

Prescriber Information

Name (first, middle, last) * Middle Name Credentials * MD DO NP PA Other

Name of Institution/Practice Name

Practice Setting * Hospital-Based Practice Practice/Group Practice

Practice Address *

City * State * Zip Code *

Preferred Method of Contact Mail E-Mail E-mail Address

Office Phone Number Mobile Phone Number Office Fax Number

Primary State License Number/State of Issue

National Provider Identification (NPI) Number *

Prescriber Specialty (Board Certification) *

Endocrinology Internal Medicine

Family Medicine

Other [please specify]

Prescriber Attestation

By signing this form I attest that:

- I understand that 1) NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism 2) NATPARA is not a parathyroid hormone replacement and 3) Because of the potential risk of osteosarcoma NATPARA is recommended only for patients who cannot be well-controlled on calcium and active forms of vitamin D alone.
- I understand there is a potential risk of osteosarcoma associated with NATPARA. NATPARA causes an increase in the incidence of osteosarcoma in rats. The increase in osteosarcoma in rats is dependent on NATPARA dose and treatment duration.
- I understand that NATPARA is only available through the NATPARA REMS Program and that I must comply with the program requirements in order to prescribe NATPARA.
- I have reviewed the Prescribing Information, the NATPARA REMS Program: An Introduction and NATPARA REMS Program Training Module for Prescribers and answered all questions included in the Knowledge Assessment.
- I understand that I must counsel my patients on the benefits and risks of NATPARA treatment, sign and submit the NATPARA REMS Program Patient-Prescriber Acknowledgment Form, and provide a copy of the NATPARA REMS Program Patient Brochure and NATPARA REMS Program Patient-Prescriber Acknowledgment Form to my patients prior to initiation of therapy.
- I agree that Shire, its agents, and contractors, such as the pharmacy, may contact me via phone, mail, or e-mail to survey me on the effectiveness of the program requirements for the NATPARA REMS Program.

Natpara
parathyroid hormone
 for injection

Introduction Training Assessment **Enrollment** Certificate

Preferred Method of Contact Mail E-Mail E-mail Address _____

Office Phone Number _____ Mobile Phone Number _____ Office Fax Number _____

Primary State License Number/State of Issue _____

National Provider Identification (NPI) Number * 1891725933

Prescriber Attestation

By signing this form I attest that:

- I understand that 1) NATPARA is a parathyroid hormone indicated as an adjunct to calcium and active forms of vitamin D alone in the treatment of hypoparathyroidism 2) NATPARA is not a parathyroid hormone replacement and 3) Because of the potential risk of osteosarcoma NATPARA is recommended to be used in conjunction with calcium and active forms of vitamin D alone
- I understand there is a potential risk of osteosarcoma associated with NATPARA. NATPARA is not recommended to be used in conjunction with calcium and active forms of vitamin D alone if there is an increase in osteosarcoma in rats is
- I understand that NATPARA is only available through the NATPARA REMS Program and that only prescribers who are enrolled in the NATPARA REMS Program may prescribe NATPARA
- I have reviewed the Prescribing Information, the NATPARA REMS Program: An Introduction and answered all questions included in the Knowledge Assessment
- I understand that I must counsel my patients on the benefits and risks of NATPARA treatment, sign and submit the NATPARA REMS Program Patient-Prescriber Acknowledgment Form, and provide a copy of the NATPARA REMS Program Patient Brochure and NATPARA REMS Program Patient-Prescriber Acknowledgement Form to my patients prior to initiation of therapy
- I agree that Shire, its agents, and contractors, such as the pharmacy, may contact me via phone, mail, or e-mail to survey me on the effectiveness of the program requirements for the NATPARA REMS Program

Signature ✕

Please use your mouse (finger tip) to sign here.

I understand that checking this box constitutes a legal signature confirming that I acknowledge and agree to the Prescriber Attestation.

Clear
Save

Prescriber Signature * _____ Date 07/07/16

Print Name * _____

Submit

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NATPARA REMS PROGRAM CERTIFICATE OF COMPLETION

Dear Prescriber,

Thank you for enrolling in the NATPARA REMS Program.

This letter and accompanying certificate confirm that you have fulfilled all REMS requirements and are now authorized to prescribe NATPARA for injection. This confirms that you have:

- Reviewed the NATPARA Prescribing Information
- Reviewed the NATPARA *REMS Program: An Introduction* information sheet
- Reviewed the NATPARA *REMS Program Training Module for Prescribers* including the Knowledge Assessment
- Successfully completed and submitted the Knowledge Assessment
- Completed, signed, and submitted one-time NATPARA *REMS Program Prescriber Enrollment Form*

Remember, before initiating treatment, prescribers must also counsel patients on the appropriate use and the benefit and risks of NATPARA. To complete the NATPARA REMS Program requirements for prescribing NATPARA:

- Download the NATPARA *REMS Program Patient Brochure* and NATPARA *REMS Program Patient-Prescriber Acknowledgment Form*
- Complete the NATPARA *REMS Program Patient-Prescriber Acknowledgment Form*
- Send the patient's prescription and the NATPARA *REMS Program Patient-Prescriber Acknowledgment Form* by
 - Fax to 1-844-NAT-REMS (628-7367) or
 - Scan and e-mail to NATPARAREMS@shire.com
- Provide patient with a copy of the NATPARA *REMS Program Patient Brochure* and NATPARA *REMS Program Patient-Prescriber Acknowledgment Form*

If you have any questions, contact the NATPARA REMS Program Coordinating Center at 1-855-NATPARA.

[Download REMS Enrollment Form](#)

[View Certificate](#)

CERTIFICATE OF COMPLETION

This Certifies that

[Redacted]

First and Last Name

[Redacted]

NPI Number

**has successfully completed the
NATPARA REMS Program Prescriber Certification**

[Redacted]

Certificate Completion Number

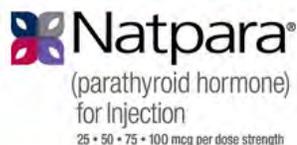
07/07/16

Date



Thank you for completing the NATPARA REMS Program Prescriber Training. Click 'Download' to download a copy of your certificate. Click 'Close' to exit the NATPARA REMS Program Prescriber Training.

[Download](#) [Close](#)



Home

Prescriber
CertificationPharmacy
Certification

NATPARA REMS Program Pharmacy Certification

To become certified, pharmacies must designate an authorized Pharmacy Representative to coordinate the setting's activities and assure compliance. The designated Pharmacy Representative must complete the following steps for certification:



1. Review the *Prescribing Information* and the *NATPARA REMS Program: An Introduction* information sheet.
2. Review the *NATPARA REMS Program: Training Module for Pharmacy Representatives* and successfully complete the Knowledge Assessment.



3. Complete and sign the *NATPARA REMS Program: Pharmacy Enrollment Form*.
4. Submit the Knowledge Assessment and the *NATPARA REMS Program: Pharmacy Enrollment Form*.

- Fax to **1-844-NAT-REMS (628-7367)** or
- Scan and e-mail to **NATPARAREMS@shire.com**

A confirmation of your certification in the NATPARA REMS Program will be sent to the pharmacy so you can begin to distribute NATPARA.

5. Ensure all relevant staff involved in dispensing NATPARA are trained on the NATPARA REMS Program requirements as described in the *NATPARA REMS Program: Training Module for Pharmacy Representatives*.
6. Put processes and procedures in place to ensure the following verifications and safe use conditions are met prior to dispensing NATPARA:
 - Verifying that the prescriber is certified in the NATPARA REMS Program by reviewing the prescriber's information against a list of REMS-certified prescribers sent from the NATPARA REMS Program Coordinating Center
 - Verifying that a *NATPARA REMS Program: Patient-Prescriber Acknowledgment Form* has been completed and submitted for the corresponding patient and prescriber by reviewing the patient and prescriber against a list of REMS-approved patients and prescribers available through the NATPARA REMS Program Coordinating Center
7. Make available to Shire and/or a designated third-party of the FDA, documentation to verify understanding of, and adherence to, the requirements of the NATPARA REMS Program.
8. Recertify in the NATPARA REMS Program if the pharmacy designates someone else as the authorized Pharmacy Representative.

If you have any questions, contact the NATPARA REMS Program Coordinating Center at **1-855-NATPARA**.

MATERIALS TO DOWNLOAD

For Pharmacies

[NATPARA Prescribing Information](#)

[NATPARA REMS Program: An Introduction](#)

[Training Module and Assessment for Pharmacies](#)

[Pharmacy Enrollment Form](#)

[NATPARA REMS Program FAQ](#)

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NATPARA REMS Program

(Risk Evaluation and Mitigation Strategy)

What is the NATPARA REMS Program?

A REMS Program is a strategy to manage known or potential serious risks associated with a drug product, and it is required by the FDA to ensure the benefits of a drug outweigh its risks. The NATPARA REMS Program informs prescribers, pharmacists, and patients about the potential risk of:

Osteosarcoma

- NATPARA causes an increase in the incidence of osteosarcoma in rats
- The increase in osteosarcoma in rats is dependent on NATPARA dose and treatment duration

Indication

NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.

Because of the potential risk of osteosarcoma, NATPARA is only recommended for patients who cannot be well-controlled on calcium and active forms of vitamin D alone and for whom the potential benefits are considered to outweigh this potential risk.

NATPARA is not a parathyroid hormone replacement.

Program Requirements

NATPARA is only available through the NATPARA REMS Program.

The requirements include:

For Prescribers

- **Certification** by completing training, including the Knowledge Assessment, and enrollment in the NATPARA REMS Program directly online or through a paper-based process by completing and submitting the completed Knowledge Assessment and the NATPARA *REMS Program: Prescriber Enrollment Form* via fax to 1-844-NAT-REMS (628-7367) or scan and email to NATPARAREMS@shire.com. [Click Here to access the Prescriber Certification page for online instructions.](#)
- **Patient counseling** on benefits and risks of NATPARA
- **Completion** of the NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* for each patient prior to initiation of treatment
- **Provide** patient with a copy of the completed NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* and the NATPARA *REMS Program: Patient Brochure*

For Pharmacies

Pharmacies must designate an authorized Pharmacy Representative who will complete the certification process on behalf of the pharmacy:

- **Certification** by completing training, including the Knowledge Assessment, and enrolling in the NATPARA REMS Program
- **Implementing** the necessary staff training and processes to comply with the NATPARA REMS Program requirements including:
 - **Verifying** that the prescriber is certified in the NATPARA REMS Program
 - **Verifying** that a NATPARA *REMS Program: Patient-Prescriber Acknowledgment Form* is on record for patient and prescriber

If you have any questions, contact the NATPARA REMS Program Coordinating Center at [1-855-NATPARA](tel:1-855-NATPARA).

MATERIALS TO DOWNLOAD

For Prescribers

- [NATPARA Prescribing Information](#)
- [NATPARA REMS Program: An Introduction Training Module and Assessment for Prescribers](#)
- [Prescriber Enrollment Form](#)
- [Patient-Prescriber Acknowledgment Form and Patient Brochure](#)
- [NATPARA REMS Program FAQ](#)

For Pharmacies

- [NATPARA Prescribing Information](#)
- [NATPARA REMS Program: An Introduction Training Module and Assessment for Pharmacies](#)
- [Pharmacy Enrollment Form](#)
- [NATPARA REMS Program FAQ](#)



Prescriber Training
and Enrollment



Pharmacist Training
and Enrollment

1 What is a Risk Evaluation and Mitigation Strategy (REMS)?

A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug or biologic beyond product labeling; it is required by the FDA if necessary to ensure that the benefits of a drug or biologic outweigh its risks.

2 Why does NATPARA have a REMS Program?

FDA has determined that a REMS is necessary to ensure that the benefits of NATPARA outweigh the potential risk of osteosarcoma.

3 What is the goal of the NATPARA REMS Program?

The goal of the NATPARA REMS Program is to mitigate the potential risk of osteosarcoma associated with NATPARA by:

- Ensuring that prescribers are educated on the following:
 - Potential risk of osteosarcoma associated with the use of NATPARA
 - Appropriate patient selection
 - Safe-use conditions required for prescribing NATPARA
- Ensuring that NATPARA is dispensed only to patients informed about the potential risk of osteosarcoma associated with the use of NATPARA

4 What are the NATPARA REMS Program requirements?

The NATPARA REMS Program requirements are as follows:

- Prescribers must become certified in the NATPARA REMS Program to be able to prescribe NATPARA
- Pharmacies must be certified to dispense NATPARA
- NATPARA must be dispensed only to patients counseled on the benefits and risks of NATPARA and after completion and submission of a *NATPARA REMS Program: Patient-Prescriber Acknowledgment Form* for each patient

5 What do I need to do in order to prescribe NATPARA?

In order to prescribe NATPARA, you need to become certified and enroll in the NATPARA REMS Program. You can complete the certification and enrollment process directly online or through a paper-based process.

A. Online

- Visit www.NATPARAREMS.com
- Click on the “Prescriber Certification” tab for instructions
- You will be required to enter your National Provider Identifier (NPI) number and your name as it appears in the NPI registry in order to initiate the online process

B. Paper-based

- Review the following:
 - *NATPARA Prescribing Information*
 - *NATPARA REMS Program: An Introduction*
 - *NATPARA REMS Program: Training Module for Prescribers*
- Successfully complete the Knowledge Assessment questions at the end of the training module (100% passing score required)
- Complete and sign the one-time *NATPARA REMS Program: Prescriber Enrollment Form*
- Submit both the completed Knowledge Assessment and *NATPARA REMS Program: Prescriber Enrollment Form* to the NATPARA REMS Program Coordinating Center via:
 - Fax at 1-844-NAT-REMS (628-7367) or
 - Scan and email to NATPARAREMS@shire.com

You will receive correspondence from the NATPARA REMS Program Coordinating Center on your certification status immediately (online) or within two (2) business days (paper-based). REMS materials may be downloaded from the REMS website at www.NATPARAREMS.com; alternatively, you may request hard copies by calling 1-855-NATPARA (628-7272).

6

What is the prescription process for NATPARA?

Once a prescriber is certified, the following steps must take place for a patient to receive NATPARA.

1. Complete the one-time *NATPARA REMS Program: Patient-Prescriber Acknowledgment Form* with each patient prior to initiation of therapy
2. Provide patients with a copy of the signed form and copy of the *NATPARA REMS Program Patient Brochure*
3. Submit the *NATPARA REMS Program: Patient-Prescriber Acknowledgment Form* and prescription to the NATPARA REMS Program Coordinating Center by fax at 1-844-NAT-REMS (628-7367) or scan and email to NATPARAREMS@shire.com
4. The NATPARA REMS Program Coordinating Center will send the prescription to a certified pharmacy to fill after verifying that the prescriber is certified and the *NATPARA REMS Program: Patient-Prescriber Acknowledgment Form* is on record
5. Certified pharmacies will not dispense NATPARA if a prescriber is not certified and/or the *NATPARA REMS Program: Patient-Prescriber Acknowledgment Form* is not on record
6. The certified pharmacy will contact the patient to arrange the date to ship NATPARA once the prescription is filled

7 Can I become certified and enroll online?

Yes, visit www.NATPARAREMS.com and click on the “Prescriber Certification” tab for instructions. You will be required to enter your National Provider Identifier (NPI) number and your name as it appears in the NPI registry in order to initiate the online process.

8 Can I become certified over the phone?

No, you will need to complete the certification and enrollment either online at www.NATPARAREMS.com or through a paper-based process as described in Question 5.

9 How long does it take to become certified?

The time to review the required training materials varies among individuals, but the Knowledge Assessment consists of seven multiple-choice questions and can generally be completed within 10 minutes.

10 I entered my NPI (National Provider Identifier) number and name to become certified online, but I received a message that the information could not be verified. What does this mean, and what should I do?

This means that either:

- The information was entered incorrectly
- The information entered does not match the information in the national NPI registry database; the name entered must match the name you provided for your NPI
- You recently received your NPI, and the database has not been updated yet

If you experience difficulties with the online certification process, you may complete hard copies of the Knowledge Assessment and *NATPARA REMS Program: Prescriber Enrollment Form* and fax them to 1-844-NAT-REMS (628-7367) or scan and email to NATPARAREMS@shire.com. You may also call the NATPARA REMS Program Coordinating Center at 1-855-NATPARA (628-7272) for assistance.

11 I am having some problems certifying online, what should I do?

If you experience difficulties with the online certification process, you may complete hard copies of the Knowledge Assessment and *NATPARA REMS Program: Prescriber Enrollment Form* and fax them to 1-844-NAT-REMS (628-7367) or scan and email to NATPARAREMS@shire.com. You may also call the NATPARA REMS Program Coordinating Center at 1-855-NATPARA (628-7272) for assistance.

12 Can I become certified even if I do not plan to write a prescription for NATPARA right away?

Yes, you can become certified without writing a prescription for NATPARA.

Prior to writing a prescription for NATPARA, it is important to have reviewed the *NATPARA Prescribing Information*, *NATPARA REMS Program: An Introduction*, and *NATPARA REMS Program: Training Module for Prescribers* to be educated on:

- The potential risk of osteosarcoma associated with the use of NATPARA
- Appropriate patient selection
- The safe-use conditions required for prescribing NATPARA, including the need to counsel patients on the potential risk of osteosarcoma associated with the use of NATPARA and the need to complete and submit a one-time *NATPARA REMS Program: Patient-Prescriber Acknowledgment Form* for each patient

13 Do I lose my certification status if I do not prescribe NATPARA?

No, healthcare professionals remain certified as long as they are compliant with the REMS Program requirements.

14 I am in a group practice; can the practice become certified as a whole?

No, the NATPARA REMS Program requires that every individual prescriber be certified in order to prescribe. Visit www.NATPARAREMS.com to become certified, or call the NATPARA REMS Program Coordinating Center at 1-855-NATPARA (628-7272) for instructions on how to become certified.

15 I am temporarily covering for another physician who is already certified. Do I need to become certified in order to prescribe NATPARA for his/her patient?

Yes, certification is required for every prescriber of NATPARA. Visit www.NATPARAREMS.com to become certified or for instructions on how to become certified, or call the NATPARA REMS Program Coordinating Center at 1-855-NATPARA (628-7272). In addition, you will need to complete and submit a one-time *NATPARA REMS Program: Patient-Prescriber Acknowledgment Form* with this patient.

16 I was referred a patient who was prescribed NATPARA from a certified prescriber. Do I need to become certified in order to prescribe and continue NATPARA treatment for this patient?

Yes, certification is required for every prescriber of NATPARA. Visit www.NATPARAREMS.com to become certified or for instructions on how to become certified, or call the NATPARA REMS Program Coordinating Center at 1-855-NATPARA (628-7272). In addition, you will need to complete and submit a one-time *NATPARA REMS Program: Patient-Prescriber Acknowledgment Form* with this patient.

17 Can a nurse practitioner and/or physician assistant become certified?

Yes, any healthcare professional with a National Provider Identifier (NPI) and license to prescribe may become certified in the NATPARA REMS Program.

18 I moved my practice to a different state; do I need to recertify?

No, the NATPARA REMS Program requires prescribers to certify one time only through their NPI, regardless of their location.

19 Do I need to recertify on a regular basis?

No, the NATPARA REMS Program requires prescribers to certify one time only.

20 What do I need to counsel my patients on?

Each patient should be counseled on the appropriate use and benefits and risks of NATPARA by reviewing the *NATPARA REMS Program Patient Brochure* and completing the *NATPARA REMS Program: Patient-Prescriber Acknowledgment Form*.

Download these materials at www.NATPARAREMS.com or call the NATPARA REMS Program Coordinating Center at 1-855-NATPARA (628-7272) to receive copies.

21 Can the NATPARA REMS Program: Patient-Prescriber Acknowledgment Form be electronically signed and submitted online?

No, the form needs to be manually signed by both the patient and prescriber and submitted to the NATPARA REMS Program Coordinating Center.

- Fax to 1-844-NAT-REMS (628-7367) or
- Scan and email to NATPARAREMS@shire.com

22 How often does a patient have to complete and sign a NATPARA REMS Program: Patient-Prescriber Acknowledgment Form?

The *NATPARA REMS Program: Patient-Prescriber Acknowledgment Form* should be completed once for each patient with their prescriber.

23 My patient signed a NATPARA REMS Program: Patient-Prescriber Acknowledgment Form at a previous physician's office. Should he/she sign another if coming to my practice?

Yes, each prescriber should sign and submit a *NATPARA REMS Program: Patient-Prescriber Acknowledgment Form* for each of their patients who will be prescribed NATPARA.

24 Can my patients go to their usual pharmacy to get their NATPARA prescription filled?

Only certified pharmacies can dispense NATPARA. The NATPARA REMS Program Coordinating Center will send the prescription to a certified pharmacy to fill after verifying that the prescriber is certified and a *NATPARA REMS Program: Patient-Prescriber Acknowledgment Form* is on record.

Certified pharmacies will not dispense NATPARA if a prescriber is not certified and/or the *NATPARA REMS Program: Patient-Prescriber Acknowledgment Form* is not on record.

The certified pharmacy will contact the patient to arrange the date to ship NATPARA once the prescription is filled.

25 My patient resides in multiple locations throughout the year. Can NATPARA be shipped to different locations?

Yes, once the prescription is filled, the certified pharmacy will contact the patient to arrange shipment.

26 How do I get copies of the NATPARA REMS Program materials?

Copies of materials can be downloaded at www.NATPARAREMS.com or obtained by calling the NATPARA REMS Program Coordinating Center at 1-855-NATPARA (628-7272).

27 I have some questions/issues about the NATPARA REMS Program. Who do I call?

If you have any questions or issues regarding the NATPARA REMS Program, please contact the NATPARA REMS Program Coordinating Center at 1-855-NATPARA (628-7272).