

## 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](http://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

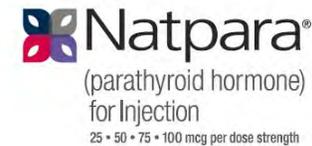
4. Implement the necessary staff training and processes to comply with the NATPARA REMS Program requirements including:
- Receiving the prescription from the NATPARA REMS Program Coordinating Center
  - Verification that prescriber is certified in the NATPARA REMS Program
  - Verification that a NATPARA *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](http://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](http://www.NATPARAREMS.com)



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NPS Pharmaceuticals, Inc. is a wholly owned, indirect subsidiary of Shire North American Group Inc.  
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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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## REMS Prescriber Training

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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

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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](http://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

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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](http://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](mailto:NATPARAREMS@shire.com)

REMS materials may be downloaded from the REMS website at [www.NATPARAREMS.com](http://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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## 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](http://www.NATPARAREMS.com)
- Call 1-855-NATPARA (628-7272)



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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 Prescribe

Click the button below to open the NATPARA Pr

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Internet Explorer

http://pi.shirecontent.com/PI/PDFs/Natpara\_USA\_ENG.pdf

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**HIGHLIGHTS OF PRESCRIBING INFORMATION**  
These highlights do not include all the information needed to use NATPARA safely and effectively. See full prescribing information for NATPARA.

**NATPARA<sup>®</sup>** (parathyroid hormone) for injection, for subcutaneous use  
Initial U.S. Approval: 01/23/2015

**WARNING: POTENTIAL RISK OF OSTEOSARCOMA**  
See full prescribing information for complete boxed warning

- In male and female rats, parathyroid hormone caused an increase in the incidence of osteosarcoma (a malignant bone tumor) that was dependent on dose and treatment duration. A risk to humans could not be excluded (5.1, 13.1)
- Because of the potential risk of osteosarcoma, prescribe NATPARA only to patients who cannot be well-controlled on calcium and active forms of vitamin D and for whom the potential benefits are considered to outweigh the potential risk. (1, 5.1)
- Avoid use of NATPARA in patients who are at increased baseline risk for osteosarcoma (including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, patients with hereditary disorders predisposing to osteosarcoma or patients with a history of prior external beam or implant radiation therapy involving the skeleton) (5.1)
- NATPARA is available only through the NATPARA REMS Program (5.2)

**INDICATIONS**  
NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism. (1)

**CONTRAINDICATIONS**  
None (4)

**WARNINGS AND PRECAUTIONS**

- Potential Risk of Osteosarcoma:** Prescribe NATPARA only to patients who cannot be well-controlled on calcium and active vitamin D. Avoid use of NATPARA in patients who are at increased risk for osteosarcoma. (5.1)
- Severe Hypercalcemia:** Monitor serum calcium when starting or adjusting NATPARA dose and when making changes to co-administered drugs known to raise serum calcium. (2.4, 5.3, 6.1)
- Severe Hypocalcemia:** Can occur with interruption or discontinuation of NATPARA treatment. Monitor serum calcium and replace calcium and vitamin D. (2.4, 5.4, 6.1)
- Digoxin Toxicity:** Hypercalcemia increases the risk of digoxin toxicity. In patients using NATPARA concomitantly with digoxin, monitor serum calcium more frequently and increase monitoring when initiating or adjusting NATPARA dose. (5.5)

**ADVERSE REACTIONS**

- The most common adverse reactions associated with NATPARA and occurring in greater than 10% of individuals were: paresthesia, nausea, hypoaesthesia, and pain in extremity (6.1)

**ADVERSE REACTIONS, contact NPS**  
Pharmaceuticals at (1-855-NATPARA) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Download (755.93 KB of 756.65 KB) : http://pi.shirecontent.com/PI/PDFs/Natpara\_USA\_ENG.pdf

## 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](#)

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## 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.

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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  
20 • 30 • 75 • 100 mg 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 web-based training interface for the NATPARA REMS Program. At the top left is the Natpara logo (parathyroid hormone for injection, 20 mcg/0.5 mL, 30 mg/0.5 mL strength). At the top right is a progress bar with five steps: Introduction, Training (highlighted), Assessment, Enrollment, and Certicate. 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 "Indication" with a decorative graphic on the right. 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 in the bottom right 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 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 (40 mg) parathyroid hormone

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 dose 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 hormone 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.

[Next](#)

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

## Screenshot #39

### Question 5 of the Knowledge Assessment

The screenshot displays the NATPARA REMS Program online prescriber certification assessment interface. At the top left, the Natpara logo is visible, including the text "(parathyroid hormone) for injection" and "20-50 IU/30mL suspension strength". A progress bar at the top right shows five steps: Introduction, Training, Assessment (highlighted), Enrollment, and Certify. Below the progress bar, a dark blue header reads "Question 5". The main content area contains the question: "How often should the NATPARA REMS Program Patient-Prescriber Acknowledgment Form be completed?". Four radio button options are listed: "With each new prescription", "With every refill", "Once a year", and "One-time for each new patient". A "Submit" button is centered below the options. 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**  
(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 injection

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

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 Certificate. 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 text are two radio button options: "True" and "False". A "Submit" button is positioned to the right of the options. At the bottom left, there are links for "Privacy Policy" and "Terms of Use". At the bottom right, a copyright notice reads: "© 2016 All rights reserved. This site is intended for U.S. residents only. NAT-019-0115 Version 1.1".

**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  
20 • 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

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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. At the top right 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: '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 located to the right of 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 on the left, and a progress bar with five stages (Introduction, Training, Assessment, Enrollment, Certificate) is on the right. The 'Assessment' stage is currently active. Below the progress bar, the title 'Question 3' is displayed in a dark blue header. The main content area contains the question: 'NATPARA causes an increase in the incidence of osteosarcoma in rats'. Two radio button options are provided: 'True' and 'False'. The 'False' option is selected. Below the options, 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 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**  
(parathyroid hormone)  
for Injection  
20 • 30 • 50 • 100 mcg 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

Below the warning, it states: "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)".

Page number: 7

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# 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/2.5 mL (100 mcg/5mL) injection strength. 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 visible. At the bottom left, 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 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  
50 mcg/2.5 mL (100 mcg/5mL) injection strength

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

Previous Slide Next Slide

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 assessment interface. At the top left is the Natpara logo with the text "parathyroid hormone for injection" and "24-36-75 mg/300 units (300 units/30 mg)". At the top right is a progress bar with five steps: Introduction, Training, Assessment (highlighted), Enrollment, and Certify. Below the progress bar is a dark blue header with "Question 4". The main content area contains the question: "Avoid use of NATPARA in patients who are at increased risk of osteosarcoma, such as:". There are 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" (selected), and "All of the above". Below the options, a red message states: "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." A blue button labeled "Review Training" is centered below the message. At the bottom left 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  
24-36-75 mg/300 units (300 units/30 mg)

Introduction Training **Assessment** Enrollment Certify

### 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

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 #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 (active), Assessment, Enrollment, and Certicate. Below the tabs 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 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 shows a web-based training interface for the NATPARA REMS Program. At the top, there is a navigation bar with the following tabs: Introduction, Training (which is 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 slide titled "NATPARA REMS Program Information". The slide includes a "Program Overview" section with the following bullet points:

- 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

At the bottom of the slide, there is a "Return to Question" button. The slide number "10" is visible in the bottom right corner. The Natpara logo is present in the top left and bottom right of the slide content. Navigation arrows for "Previous Slide" and "Next Slide" are located on the left and right sides of the slide respectively. At the bottom of the interface, there is a checkbox labeled "I have reviewed the slide(s)" and a footer containing "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 #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 with the text "(parathyroid hormone) for injection" and "20-50 mg/30-minute dose strength". At the top right is a progress bar with five steps: Introduction, Training (highlighted), 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 decorative graphic on the right. 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 a "Previous Slide" button on the left and a "Next Slide" button on the right. At the bottom of the slide is the Natpara logo and the number "11". 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" 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 indicates the user is in the 'Assessment' phase, with 'Introduction', 'Training', 'Enrollment', and 'Certificate' also visible. 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, a 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 (parathyroid hormone for injection) and a small graphic of four overlapping leaves in blue, red, and grey. Navigation buttons for "Previous Slide" and "Next Slide" are visible. A "Return to Question" button is located at the bottom right. A red checkmark and the text "I have reviewed the slide(s)" are visible at the bottom left. The footer includes "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 following tabs: Introduction, Training (which is highlighted), 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 features 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

At the bottom of the slide, there is a "Return to Question" button. Below the slide, there is a checkbox labeled "I have reviewed the slide(s)".

At the bottom of the page, there is a footer with the text "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 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, the Natpara logo is visible, including the text "(parathyroid hormone) for injection" and "25 • 50 • 75 • 100 mcg/0.5mL sterile solution". A progress bar at the top right shows five steps: Introduction, Training (highlighted), 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 "Patient Counseling on Benefit/Risk Profile". The slide contains the following text:

- 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

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 button labeled "Return to Question".

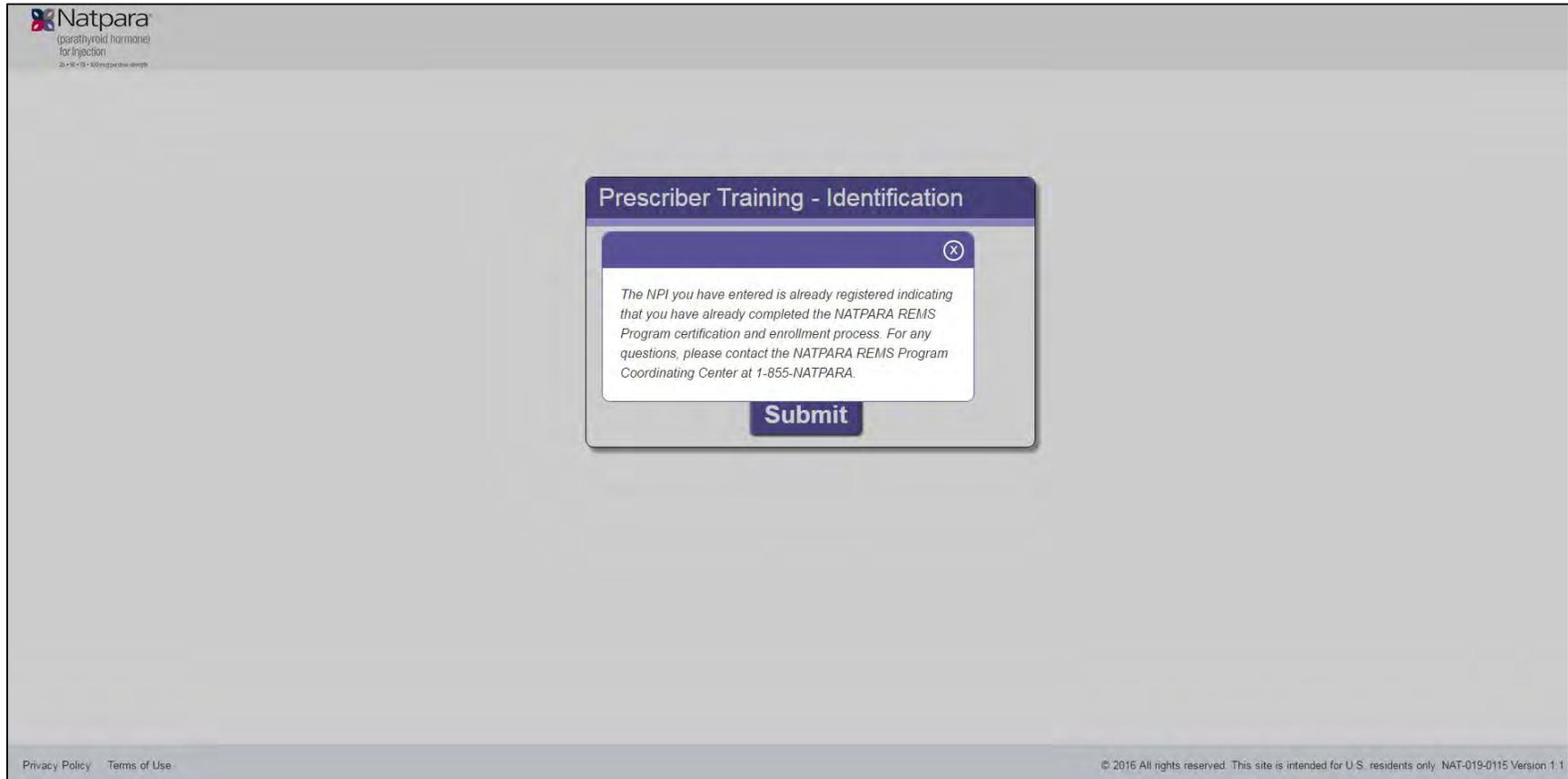
At the bottom of the interface, there are links for "Privacy Policy" and "Terms of Use" on the left, and a copyright notice "© 2016 All rights reserved. This site is intended for U.S. residents only. NAT-019-0115 Version 1.1" on the right.

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

### Screenshot #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.***

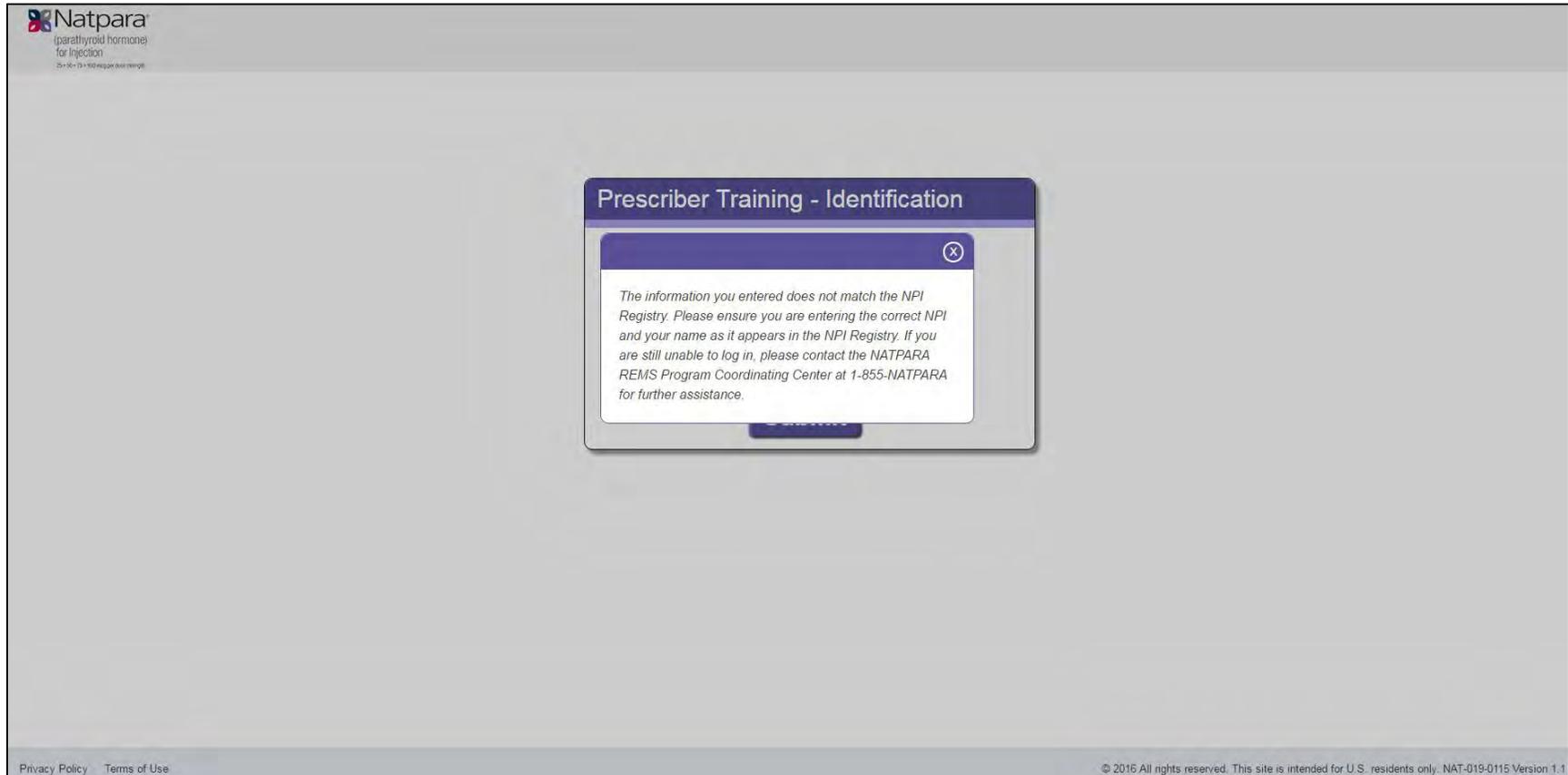


## NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

### 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.***

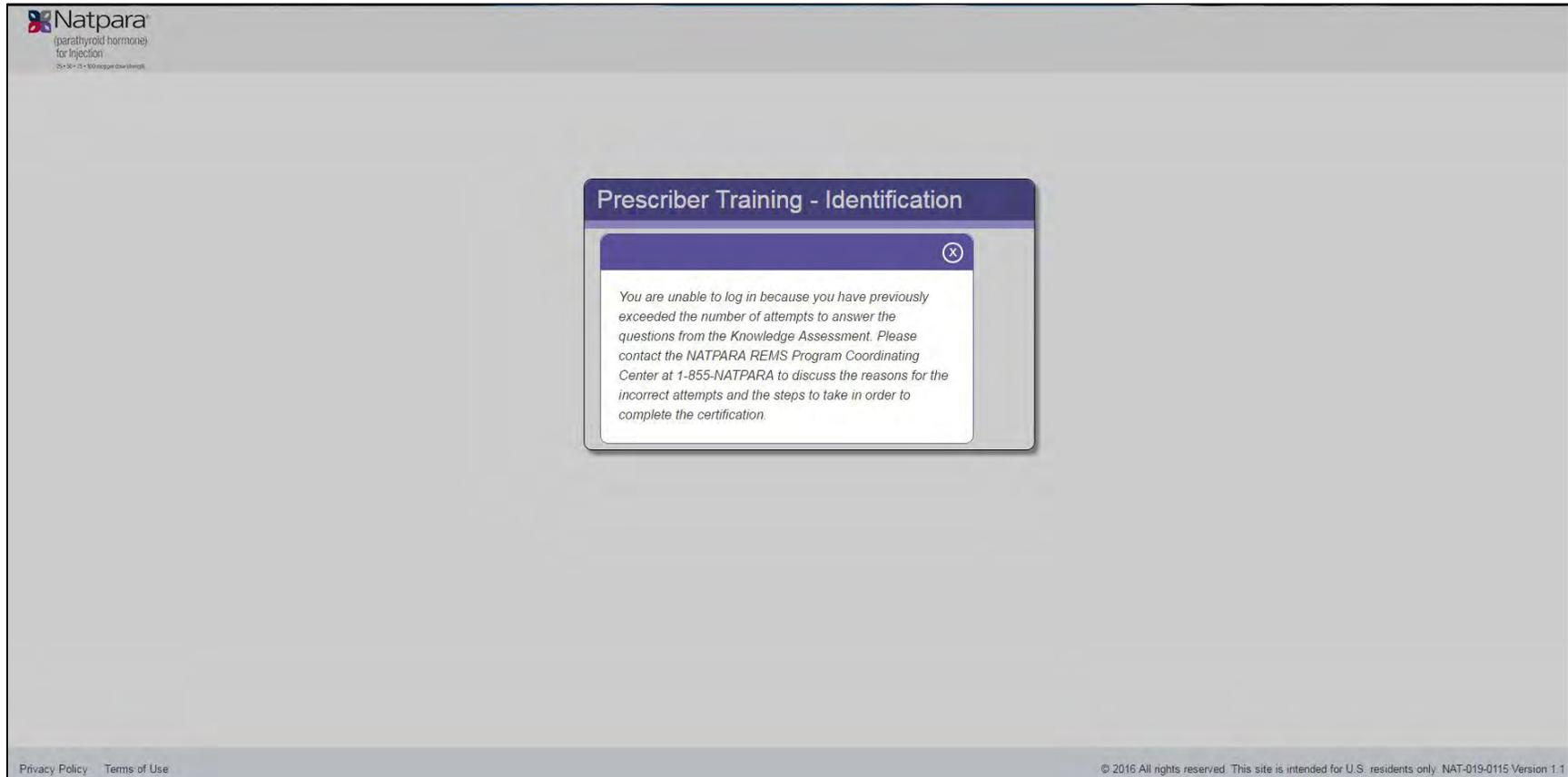
The screenshot displays the NATPARA REMS Program online prescriber certification interface. At the top left is the Natpara logo (parathyroid hormone for injection) and at the top right is a progress bar with five steps: Introduction, Training, Assessment, Enrollment, and Certify. The current step is Assessment. Below the progress bar is a dark blue header with the text "Question 3". The main content area shows a question: "NATPARA causes an increase in the incidence of osteosarcoma in rats" with two radio button options: "True" and "False". The "False" option is selected. A white pop-up message box with a purple header "Exceeded Attempts" and a close button is centered on the screen. The message text reads: "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 of the interface 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 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

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 can prescribe NATPARA
- I have reviewed the Prescribing Information, the NATPARA REMS Program: An Introduction to the Program, 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

**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](mailto: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