

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.

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

Screenshot #1

Screenshot of log-in page of when an HCP clicks on the button “Begin Online Certification and Enrollment” located on the Prescriber Certification Landing page.

The screenshot shows a web page for Natpara (parathyroid hormone) for injection. The main content is a form titled "Prescriber Training - Identification". The form contains three input fields: "NPI *", "First Name *", and "Last Name *", each followed by a text box. Below the fields is a blue "Submit" button. The page footer 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
(parathyroid hormone)
for injection
25 • 36 • 75 • 100mcg per dose strength

Prescriber Training - Identification

NPI *

First Name *

Last Name *

Submit

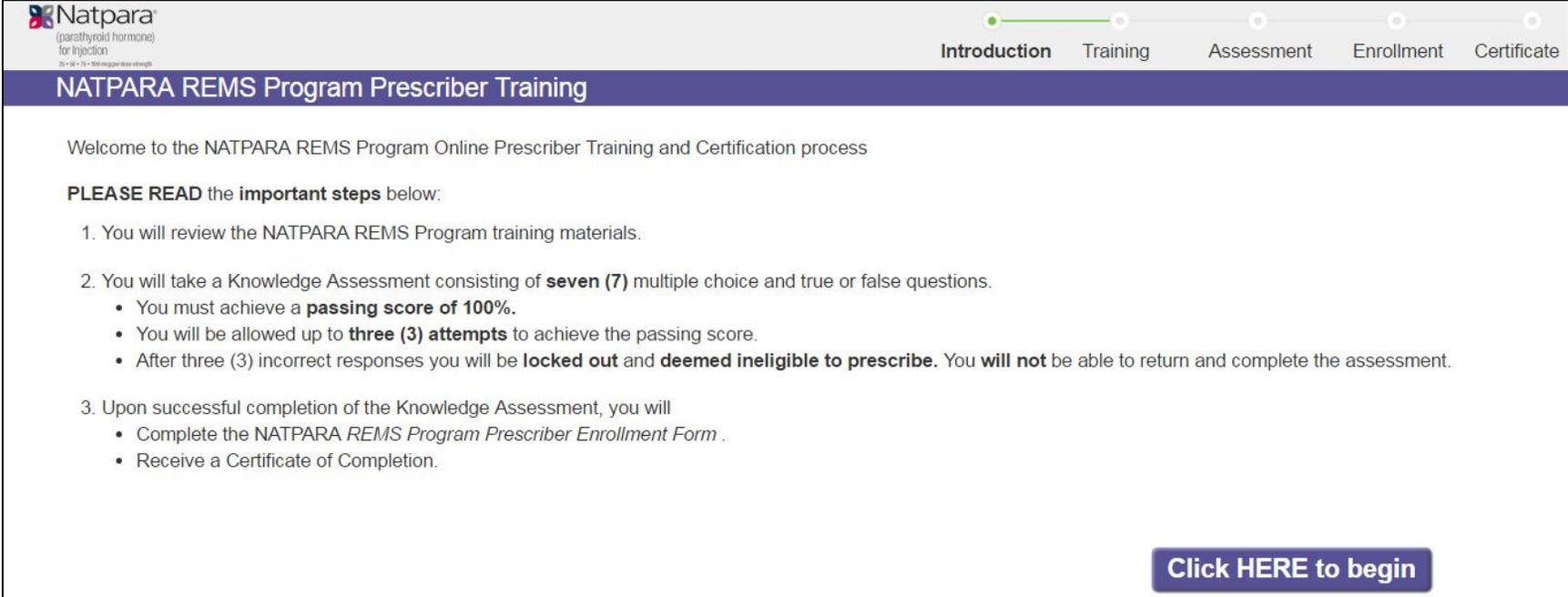
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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #2

Introduction to NATPARA REMS Program Prescriber Training



The screenshot shows a web page for the NATPARA REMS Program Prescriber Training. At the top left is the Natpara logo, which includes the text "(parathyroid hormone) for injection" and "20-80-70 • 500mg per dose vial". At the top right is a progress bar with five steps: Introduction, Training, Assessment, Enrollment, and Certificate. The "Introduction" step is currently active, indicated by a green dot and a line. Below the progress bar is a dark blue header with the text "NATPARA REMS Program Prescriber Training". The main content area has a white background and contains the following text:

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.

At the bottom right of the page is a dark blue button with the text "Click HERE to begin".

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

Screenshot #3

Review of the NATPARA *REMS Program: An Introduction*; user is able to scroll through the document.

The screenshot displays the 'NATPARA REMS Program Prescriber Training' interface. At the top left is the Natpara logo (parathyroid hormone for injection, 20 mcg/20 mL injection per dose strength). A progress bar at the top right shows five steps: Introduction (active), Training, Assessment, Enrollment, and Certificate. The main content area is titled 'NATPARA REMS Program: An Introduction' and includes a document toolbar. The text reads: '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.' Below this is a section titled 'NATPARA REMS Program Requirements' with a bulleted list: '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', and 'Only certified pharmacies can dispense NATPARA'. The next section is 'Prescriber Certification', with the text: 'Prescriber certification and enrollment can be completed directly online at www.NATPARAREMS.com or through a paper-based process as follows:'. At the bottom left, there is a checkbox labeled 'I have reviewed the 'NATPARA REMS Program: An Introduction''. At the bottom right, there is a 'Next' button.

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

Screenshot #4

User must check “I have reviewed the NATPARA REMS Program: An Introduction” checkbox in order to proceed to the NATPARA REMS Program Training Module for Prescribers.

Natpara
(parathyroid hormone)
for Injection
25 • 50 • 75 • 100 mcg per dose strength

Introduction **Training** Assessment Enrollment Certify

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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Natpara[®]
(parathyroid hormone)
for Injection
25 • 50 • 75 • 100 mcg per dose strength

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

Next

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

Screenshot #5

Review of the NATPARA REMS Program Training Module for Prescribers:

Users manually advance through the slides at their own pace by clicking on the “Next Slide” arrow located to the right of the slide. Users also have the ability to go back to the previous slide by clicking on the “Previous Slide” arrow located to the left of the slide. Clicking on the “Previous Document” button at the bottom right corner lead users to the previous document reviewed (in this case, the NATPARA REMS Program: An Introduction). Users cannot proceed to the next document until they advanced through all the slides.

The screenshot displays a web-based training interface. At the top left is the Natpara logo with the text "(parathyroid hormone) for injection" and "20 • 30 • 75 • 100 mcg per dose strength". At the top right is a progress bar with five stages: 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 white box with the following text: "NATPARA® (parathyroid hormone) for injection", "Risk Evaluation and Mitigation Strategy (REMS) Program", and "PRESCRIBER TRAINING MODULE". To the left of the box is a "Previous Slide" button with a left arrow, and to the right is a "Next Slide" button with a right arrow. At the bottom left, there is a checkbox with the text "I have reviewed the NATPARA REMS Program Training Module for Prescribers". At the bottom right, there are two buttons: "Previous Document" and "Next".

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

Screenshot #6

Slide 2 of NATPARA REMS Program Training Module for Prescribers

Natpara
(parathyroid hormone)
for injection
20-46170-0100/par for slide 2 through

Introduction Training Assessment Enrollment Certicate

REMS Prescriber Training

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

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I have reviewed the NATPARA REMS Prescriber Training Module

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

Screenshot #7

Slide 3 of NATPARA REMS Program Training Module for Prescribers

Natpara
(parathyroid hormone)
for injection
20 • 30 • 75 • 150mcg per dose strength

Introduction **Training** Assessment Enrollment Certicate

NATPARA REMS Program Prescriber Training

Introduction

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I have reviewed the NATPARA REMS Program Training Module for Prescribers

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

Screenshot #9

Slide 5 of NATPARA REMS Program Training Module for Prescribers

Natpara
(parathyroid hormone)
for injection

Introduction **Training** Assessment Enrollment Certicate

NATPARA REMS Program Prescriber Training

NATPARA®
(parathyroid hormone) for injection

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I have reviewed the NATPARA REMS Program Training Module for Prescribers

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

Screenshot #10

Slide 6 of NATPARA REMS Program Training Module for Prescribers

Natpara
(parathyroid hormone)
for injection
20 • 50 • 75 • 100 mcg per dose strength

Introduction **Training** Assessment Enrollment Certicate

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

I have reviewed the NATPARA REMS Program Training Module for Prescribers

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

Screenshot #11

Slide 7 of NATPARA REMS Program Training Module for Prescribers

Natpara
(parathyroid hormone)
for Injection
20 • 30 • 70 • 90 mcg per dose strength

Introduction **Training** Assessment Enrollment Certicate

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

I have reviewed the NATPARA REMS Program Training Module for Prescribers

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

Screenshot #12

Slide 8 of NATPARA REMS Program Training Module for Prescribers

The screenshot displays a training slide titled "Appropriate Patient Selection" within the "NATPARA REMS Program Prescriber Training" interface. The interface includes a top navigation bar with the Natpara logo and a progress indicator showing the current slide is "Training". The slide content is as follows:

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

Navigation controls include "Previous Slide" and "Next Slide" buttons. At the bottom, there is a checkbox for "I have reviewed the NATPARA REMS Program Training Module for Prescribers" and "Previous Document" and "Next" buttons. 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 #13

Slide 9 of NATPARA REMS Program Training Module for Prescribers

Natpara
(parathyroid hormone)
for Injection
25 • 50 • 75 • 100 mcg/0.5mL dose strength

Introduction **Training** Assessment Enrollment Certicate

NATPARA REMS Program Prescriber Training

NATPARA REMS Program Information

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I have reviewed the NATPARA REMS Program Training Module for Prescribers

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

Screenshot #14

Slide 10 of NATPARA REMS Program Training Module for Prescribers

Natpara
(parathyroid hormone)
for Injection
25 • 30 • 50 • 100 mcg/0.5 mL strength

Introduction **Training** Assessment Enrollment Certificate

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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I have reviewed the NATPARA REMS Program Training Module for Prescribers

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

Screenshot #15

Slide 11 of NATPARA REMS Program Training Module for Prescribers

Natpara
(parathyroid hormone)
for Injection
20 • 30 • 70 • 100 mcg powder strength

Introduction **Training** Assessment Enrollment Certify

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

I have reviewed the NATPARA REMS Program Training Module for Prescribers

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

Screenshot #16

Slide 12 of NATPARA REMS Program Training Module for Prescribers

Natpara
(parathyroid hormone)
for Injection
20 • 30 • 50 • 80 mg powder strength

Introduction **Training** Assessment Enrollment Certicate

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)

Natpara
(parathyroid hormone)
for Injection
20 • 30 • 50 • 80 mg powder strength

12

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I have reviewed the NATPARA REMS Program Training Module for Prescribers

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

Screenshot #17

Slide 13 of NATPARA REMS Program Training Module for Prescribers

Natpara
(parathyroid hormone)
for Injection
25 • 50 • 75 • 100 mcg/0.5mL strength

Introduction **Training** Assessment Enrollment Certificate

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 – Online Prescriber Certification Screen Captures (ALL)

Screenshot #18

Slide 14 of NATPARA REMS Program Training Module for Prescribers

The screenshot shows a training slide titled "Prescription Process" within the "NATPARA REMS Program Prescriber Training" module. The slide is part of a five-step process: Introduction, Training, Assessment, Enrollment, and Certicate. The "Training" step is currently active. The slide content includes a list of instructions for prescribers regarding the completion and submission of the Patient-Prescriber Acknowledgment Form, patient education, and the role of the coordinating center and pharmacy. A progress bar at the top indicates the current position in the training. Navigation buttons for "Previous Slide" and "Next Slide" are visible on the left and right sides of the slide content. At the bottom, there is a checkbox for "I have reviewed the NATPARA REMS Program Training Module for Prescribers" and buttons for "Previous Document" and "Next".

Natpara
(parathyroid hormone)
for Injection
25 • 30 • 35 • 50 mcg per dose strength

Introduction Training Assessment Enrollment Certicate

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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I have reviewed the NATPARA REMS Program Training Module for Prescribers

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

Screenshot #19

Slide 15 of NATPARA REMS Program Training Module for Prescribers

Natpara
(parathyroid hormone)
for injection
35 • 60 • 75 • 100 mg/0.5 mL strength

Introduction **Training** Assessment Enrollment Certificate

NATPARA REMS Program Prescriber Training

Questions about the NATPARA REMS Program

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I have reviewed the NATPARA REMS Program Training Module for Prescribers

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

Screenshot #20

Slide 16 of NATPARA REMS Program Training Module for Prescribers

Users must check the box “I have reviewed the NATPARA REMS Program Training Module for Prescribers” in order to advance to the next step

Natpara
(parathyroid hormone)
for Injection
20 • 30 • 50 • 100 mcg/0.5 mL dose strength

Introduction **Training** Assessment Enrollment Certificate

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 – Online Prescriber Certification Screen Captures (ALL)

Screenshot #21

Review of the NATPARA Prescribing Information

Users cannot proceed to the next step until they have opened and acknowledged their review of the NATPARA Prescribing Information

Natpara
(parathyroid hormone)
for injection
20 • 30 • 40 • 60 mg/0.5 mL strength

Introduction **Training** Assessment Enrollment Certificate

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 – Online Prescriber Certification Screen Captures (ALL)

Screenshot #22

The NATPARA Prescribing Information document opens when clicking on the button “Open NATPARA Prescribing Information”.

The screenshot displays the NATPARA REMS Program website. On the left, the Natpara logo is visible, along with the text "parathyroid hormone for injection" and "24-36-75-100 mcg glass dose strength". Below the logo, the heading "NATPARA REMS Program Prescribe" is partially visible. A button labeled "Open NATPARA Prescribing Information" is prominent. Below the button, there is a checkbox with the text "I have reviewed the NATPARA Prescribing Information".

Overlaid on the website is a preview of the NATPARA Prescribing Information document. The document title is "http://pi.shirecontent.com/PI/PDFs/Natpara_USA_ENG.pdf - Internet Explorer". The document content includes:

- 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® (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)
- DOSAGE FORMS AND STRENGTHS**
NATPARA is supplied as a multiple dose, dual-chamber glass cartridge containing a sterile lyophilized powder and a sterile diluent for reconstitution in four dosage strengths.
For injection: 25 mcg, 50 mcg, 75 mcg, or 100 mcg
- 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)

At the bottom of the document preview, it states: "NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism. (1) Pharmaceuticals at (1-855-NATPARA) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch."

The browser status bar shows "Downloading (755.93 KB of 756.65 KB) : http://pi.shirecontent.com/PI/PDFs/Natpara_USA_ENG.pdf".

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

Screenshot #23

Review of the NATPARA Prescribing Information:

Users are able to scroll through the document at their own pace.

Click the button below to open the NATPARA Prescribing Information

Open NATPARA Prescribing Information

I have reviewed the NATPARA Prescribing Information

	Mean (SD) *	n (%)	(p < 0.001)
Oral Active Vitamin D Reduction \geq 50% - n (%)		18 (45.0)	73 (86.9)
ACSC maintained between \geq 7.5 mg/dL to \leq ULN - n (%)		35 (87.5)	73 (86.9)

ACSC = albumin-corrected total serum calcium; EOT = end of treatment; N = total number of subjects; n = number of subjects meeting the specified endpoint; SD = standard deviation; ULN = upper limit of normal
 * Based on Analysis of Covariance (ANCOVA) model with percent change as the dependent variable and the treatment as the factor and baseline calcium dose as the covariate.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

NATPARA (parathyroid hormone) for injection for subcutaneous use is supplied as a medication cartridge, which is comprised of a multiple dose, dual-chamber glass cartridge containing a sterile lyophilized powder and a sterile diluent, within a plastic cartridge holder. The medication cartridge is available in 4 dosage strengths (25, 50, 75, and 100 mcg/dose). The 25 mcg/dose cartridge contains 0.40 mg parathyroid hormone; the 50 mcg/dose cartridge contains 0.80 mg parathyroid hormone; the 75 mcg/dose cartridge contains 1.21 mg parathyroid hormone; the 100 mcg/dose cartridge contains 1.61 mg parathyroid hormone.

NATPARA is supplied in the following packages:

- 2 cartridges of 25 mcg/dose strength (NDC 68875-0202-2)
- 2 cartridges of 50 mcg/dose strength (NDC 68875-0203-2)
- 2 cartridges of 75 mcg/dose strength (NDC 68875-0204-2)
- 2 cartridges of 100 mcg/dose strength (NDC 68875-0205-2)

Next

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

Screenshot #24

Review of the Prescribing Information:

Upon completion of review, users must check the box “I have reviewed the NATPARA Prescribing Information” in order to proceed to the next step.

Natpara
(parathyroid hormone)
for Injection

Introduction **Training** Assessment Enrollment Certificate

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

Previous **Next**

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

Screenshot #25

Users are able to download the materials reviewed.

Natpara
(parathyroid hormone)
for Injection
200 I.U./mL (100mcg per 0.5mL strength)

Introduction **Training** Assessment Enrollment Certify

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

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

Screenshot #26

NATPARA REMS Program Prescriber Knowledge Assessment introduction

The screenshot shows the introduction page for the NATPARA REMS Program Prescriber Knowledge Assessment. At the top left is the Natpara logo, which includes the text "(parathyroid hormone) for injection" and "100 mcg/30L (300 USP units/30mL) sterile solution". At the top right is a progress bar with five steps: Introduction, Training, Assessment, Enrollment, and Certify. The "Assessment" step is currently selected and highlighted in green. Below the progress bar is a dark blue header with the text "NATPARA REMS Program Prescriber Knowledge Assessment". The main content area contains the following text and list:

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.

At the bottom center of the main content area is a blue button with the text "START".

At the bottom left of the page is the text "Privacy Policy Terms of Use". At the bottom right is 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 #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

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

Screenshot #28

Question 1 of the Knowledge Assessment

Users must select an answer and hit “Submit”.

Natpara
(parathyroid hormone)
for injection
25 • 36 • 75 • 100mcg per dose strength

Introduction Training **Assessment** Enrollment Certify

Question 1

NATPARA is only available through the NATPARA REMS Program

True

False

Submit

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

Screenshot #29

Question 1 of the Knowledge Assessment answered correctly

The screenshot shows a web interface for the NATPARA REMS Program. At the top left is the Natpara logo with the text "(parathyroid hormone) for injection" and "24 • 36 • 72 • 90 mcg per dose strength". At the top right is a progress bar with five stages: Introduction, Training, Assessment, Enrollment, and Certify. The "Assessment" stage is currently active. Below the progress bar is a dark blue header with the text "Question 1". The main content area contains the question: "NATPARA is only available through the NATPARA REMS Program". There are two radio button options: "True" (which is selected) and "False". Below the options, it says "Your answer is correct." followed by a paragraph of text: "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." At the bottom center of the question area is a blue button labeled "Next". 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 REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #30

Question 2 of the Knowledge Assessment



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

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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
25 • 36 • 75 • 100mcg 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 (parathyroid hormone for injection, 20 • 30 • 75 • 100mcg per 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 white box with the title "Indication" and a decorative graphic of four overlapping circles in blue, red, and purple. The text in the box states: "NATPARA is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism." It lists two main points: "NATPARA is not a parathyroid hormone replacement" and "Limitations of Use:", which includes three sub-points: "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 and a small number "6" are in the bottom right of the box. At the bottom left of the slide is a checkbox labeled "I have reviewed the slide(s)". At the bottom right is a blue button labeled "Return to Question". 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



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

Submit

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

Screenshot #34

Question 2 of the Knowledge Assessment answered correctly



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.

Next

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

Screenshot #35

Question 3 of the Knowledge Assessment



Introduction Training **Assessment** Enrollment Certificate

Question 3

NATPARA causes an increase in the incidence of osteosarcoma in rats

True

False

Submit

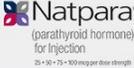
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NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

Screenshot #36

Question 3 of the Knowledge Assessment answered correctly



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



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

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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 Certicate

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 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



Introduction Training **Assessment** Enrollment Certicate

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



Introduction Training **Assessment** Enrollment Certicate

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



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



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



Introduction Training **Assessment** Enrollment Certificate

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



Introduction Training **Assessment** Enrollment Certificate

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)

Screenshot #45

Conclusion of the Knowledge Assessment

The screenshot displays the 'Conclusion' page of the NATPARA REMS Program Prescriber Certification process. At the top left is the Natpara logo, which includes a stylized four-leaf clover icon and the text 'Natpara® (parathyroid hormone) for Injection 25 • 50 • 75 • 100 mcg per dose strength'. To the right of the logo is a progress bar with five circular markers. The first three markers are filled with green, and the fourth is partially filled, while the fifth is empty. Below the progress bar are the labels 'Introduction', 'Training', 'Assessment', 'Enrollment', and 'Certificate'. The 'Assessment' label is bolded, indicating the current step. Below the progress bar is a dark blue header with the word 'Conclusion' in white. The main content area has a white background and contains the following text: 'Thank you for completing the NATPARA REMS Program Prescriber Knowledge Assessment.' followed by 'To become certified to prescribe NATPARA, you will need to complete and sign the NATPARA REMS Program Prescriber Enrollment Form.' Below this text is a large, dark blue button with the text 'Enroll Now' in white. At the bottom of the page, there is a light blue footer containing the links 'Privacy Policy' and 'Terms of Use' on the left, and the 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 #46

NATPARA REMS Program Prescriber Enrollment Form; name and NPI number are pre-populated; users must fill out the remaining fields.

Natpara
(parathyroid hormone)
for injection
25 • 30 • 35 • 40 mg per dose strength

Introduction Training Assessment **Enrollment** Certification

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 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 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

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

Screenshot #47

Signature box pops-up when clicking on the prescriber signature line that says “Click here to sign”; pop-up box instructs users to “Please use your mouse or fingertip to sign here.”

Natpara
(parathyroid hormone)
for Injection

2016-10-10 10:00:00 AM EDT

Introduction Training Assessment **Enrollment** Certify

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 for 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 combination with calcium and active forms of vitamin D alone
- I understand there is a potential risk of osteosarcoma associated with NATPARA. NATPARA is recommended to be used in combination with calcium and active forms of vitamin D alone. The risk of osteosarcoma is dependent on NATPARA dose and treatment duration
- I understand that NATPARA is only available through the NATPARA REMS Program and that the program is designed to minimize the risk of osteosarcoma
- I have reviewed the Prescribing Information, the NATPARA REMS Program: An Introduction to the Program, and the NATPARA REMS Program Patient-Prescriber Acknowledgment Form 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

Prescriber Signature * _____ Date 07/07/16

Print Name * _____

Signature [X]

Please use your mouse or fingertip 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**

Submit

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

Screenshot #48

Handwritten signature is applied in the signature box using a mouse (computer) or fingertip (tablet); users have the ability to redo their signature by hitting the “clear” button; users must check the box “I understand that checking this box constitutes a legal signature confirming that I acknowledge and agree to the Prescriber Attestation” in order to save and proceed with the enrollment.

Natpara
(parathyroid hormone)
for Injection

20-18-15-10 registration through

Introduction Training Assessment **Enrollment** Certify

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 reserved for use in the treatment of hypoparathyroidism
- I understand there is a potential risk of osteosarcoma associated with NATPARA. NATPARA is not a parathyroid hormone replacement and active forms of vitamin D alone 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 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 the NATPARA REMS Program Knowledge Assessment 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 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 – Online Prescriber Certification Screen Captures (ALL)

Screenshot #49

The handwritten signature is applied and embedded in the PDF document.



Introduction Training Assessment **Enrollment** Certificate

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

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

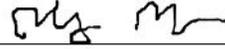
Primary State License Number/State of Issue _____

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 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

Prescriber Signature *  _____ Date 07/07/16

Print Name * _____

Submit

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

Screenshot #50

NATPARA REMS Program Certificate of Completion Thank you page is displayed; users have the ability to download the REMS Enrollment Form and view the NATPARA REMS Program Certificate.

NATPARA
operational medicines
for Injection

Introduction Training Assessment Enrollment Certificate

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](#)

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

Screenshot #51

Users hit “View Certificate” to view and/or download the Certificate of Completion; the session ends when user hit the “Close” button.

The screenshot displays the 'Certificate of Completion' screen for the NATPARA REMS Program Prescriber Certification. The page features a navigation bar at the top with the following steps: Introduction, Training, Assessment, Enrollment, and Certificate. The main content area is titled 'CERTIFICATE OF COMPLETION' and includes the following information:

- This Certifies that**
- SILVINA LEWIS-BOSSCAO** (Redacted)
- First and Last Name
- 1007120000** (Redacted)
- NPI Number
- has successfully completed the NATPARA REMS Program Prescriber Certification**
- [Redacted]** (Redacted)
- Certificate Completion Number
- 07/07/16**
- Date

The Shire logo is visible in the bottom left corner, and the Natpara logo is in the bottom right corner. Below the certificate information, a message reads: "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." Two buttons, 'Download' and 'Close', are located at the bottom of the main content area. 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)

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 Certify

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 mL suspension". At the top right, a progress bar indicates the current step is "Training", with other steps being "Introduction", "Assessment", "Enrollment", and "Certificate". The main content area features a slide titled "Introduction" with the following text:

- 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 button labeled "Return to Question". 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 #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 interface. At the top left, the Natpara logo is shown with the text "(parathyroid hormone) for Injection" and "20 • 30 • 75 • 90 mg per dose strength". At the top right, a progress bar indicates the user is in the "Assessment" phase, with "Introduction", "Training", "Assessment", "Enrollment", and "Certificate" stages marked. 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" (unselected) and "False" (selected). A red message states: "Your answer is incorrect." Below that, another red message reads: "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 messages. 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 #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 slide from the NATPARA REMS Program Prescriber Training. The slide features the Natpara logo (parathyroid hormone for injection, 20-30-70-100mcg per dose strength) in the top left corner. A progress bar at the top right indicates the current slide is in the 'Training' phase, with other phases being 'Introduction', 'Assessment', 'Enrollment', and 'Certificate'. The slide title is 'NATPARA REMS Program Prescriber Training'. The main content is a 'Boxed Warning' with the following text:

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*

The slide also includes 'Previous Slide' and 'Next Slide' navigation buttons. 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 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 training slide titled "Appropriate Patient Selection" within the "NATPARA REMS Program Prescriber Training" interface. The slide content is as follows:

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

Navigation controls include "Previous Slide" and "Next Slide" buttons. A checkbox at the bottom left is labeled "I have reviewed the slide(s)". A "Return to Question" button is located at the bottom right. 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 #57

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



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, 20-100 IU/0.5 mL (100 mcg/0.5 mL) per 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 "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:" followed by a bulleted list: "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 Natpara logo is also present in the bottom right corner of the slide. Below the slide, there is a checkbox labeled "I have reviewed the slide(s)" and a "Return to Question" button. 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
(parathyroid hormone)
for injection
20-100 IU/0.5 mL (100 mcg/0.5 mL) per dose 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

I have reviewed the slide(s)

[Return to Question](#)

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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 • 75 • 90 mg per dose 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

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.

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

Introduction **Training** Assessment Enrollment Certificate

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

[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 #61

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

Natpara
(parathyroid hormone)
for injection
20-35-70-150mcg per dose strength

Introduction **Training** Assessment Enrollment Certicate

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*

[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 #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 stages: 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, 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 training slide for NATPARA. At the top, there is a progress bar with five steps: Introduction, Training, Assessment, Enrollment, and Certify. The 'Training' step is currently active. The slide title is 'NATPARA REMS Program Prescriber Training'. The main content area 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

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 'Return to Question' button. The slide also features 'Previous Slide' and 'Next Slide' navigation arrows. The Natpara logo is visible in the top left and bottom right corners of the slide content area.

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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 training slide for NATPARA. At the top left is the Natpara logo (parathyroid hormone) for injection, 20-30 IU/10mL single dose 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 is white and contains a slide titled 'Appropriate Patient Selection'. 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 features a 'Previous Slide' button on the left and a 'Next Slide' button on the right. 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
20-30 IU/10mL single dose 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 #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, a progress bar shows five stages: Introduction, Training, Assessment (highlighted), Enrollment, and Certificate. The main content area is titled "Question 7" and contains the following text:

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

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](#)

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 shown with the text "(parathyroid hormone) for injection" and "20 • 30 • 75 • 100 mcg per dose strength". To the right, a progress bar indicates the current slide is in the "Training" phase, with other phases being "Introduction", "Assessment", "Enrollment", and "Certificate". Below the progress bar, a dark blue header reads "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, there is a checkbox labeled "I have reviewed the slide(s)". At the bottom right of the slide, there is a "Return to Question" button. The Natpara logo and the number "13" are visible in the bottom right corner of the slide.

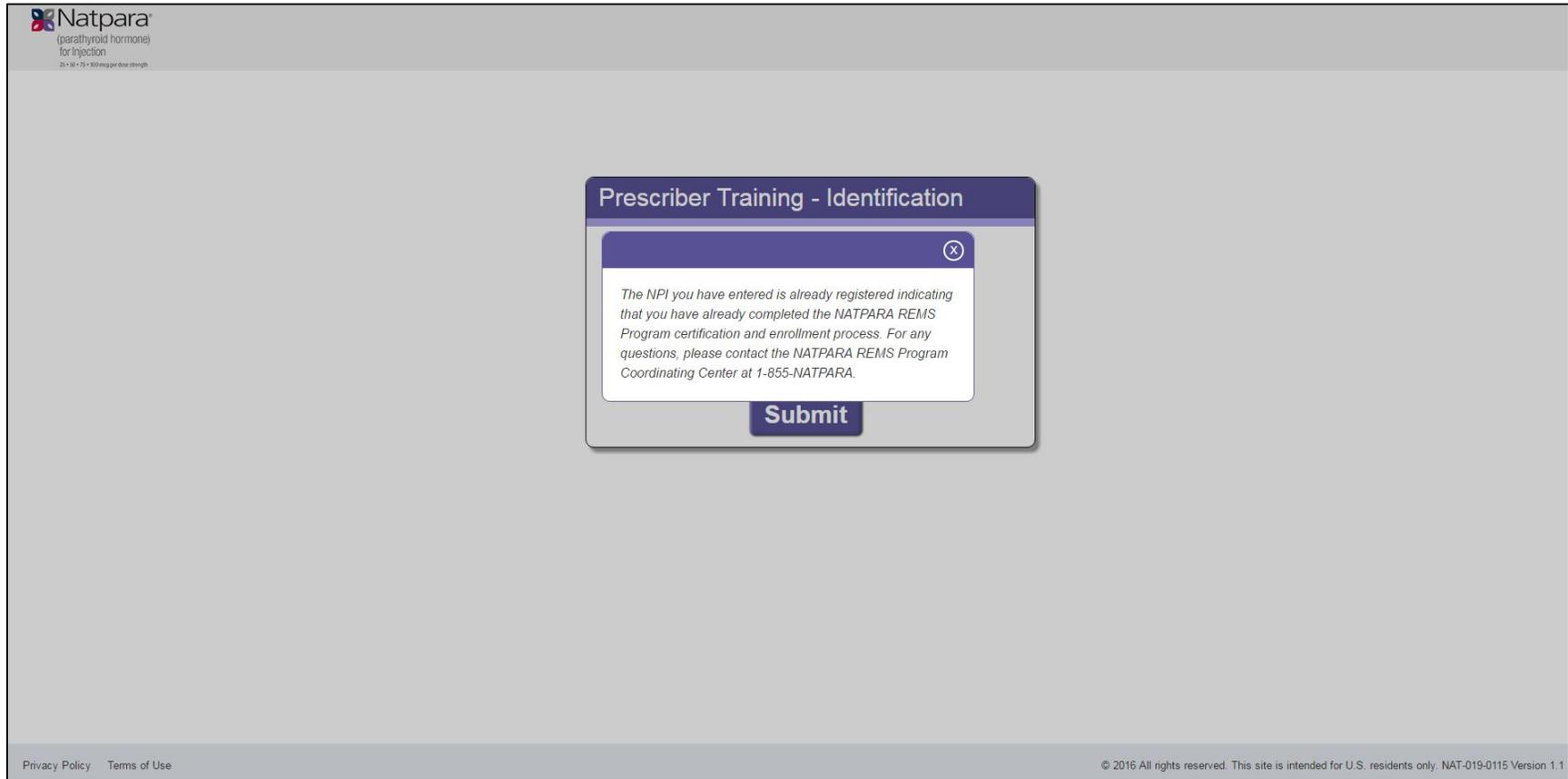
At the bottom of the interface, there are links for "Privacy Policy" and "Terms of Use" on the left, and a copyright notice "© 2016 All rights reserved. This site is intended for U.S. residents only. NAT-019-0115 Version 1.1" on the right.

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.

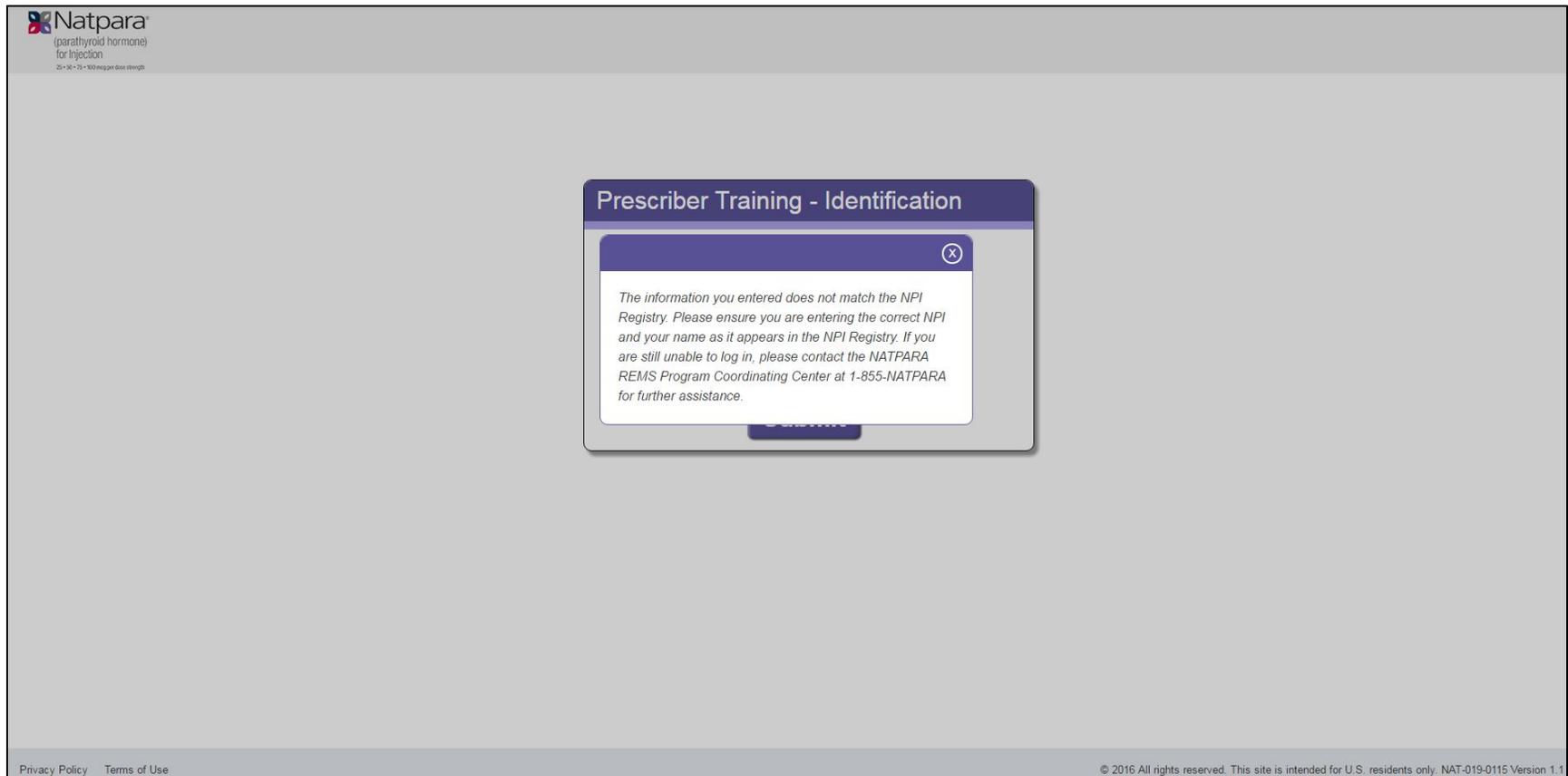


NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

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.

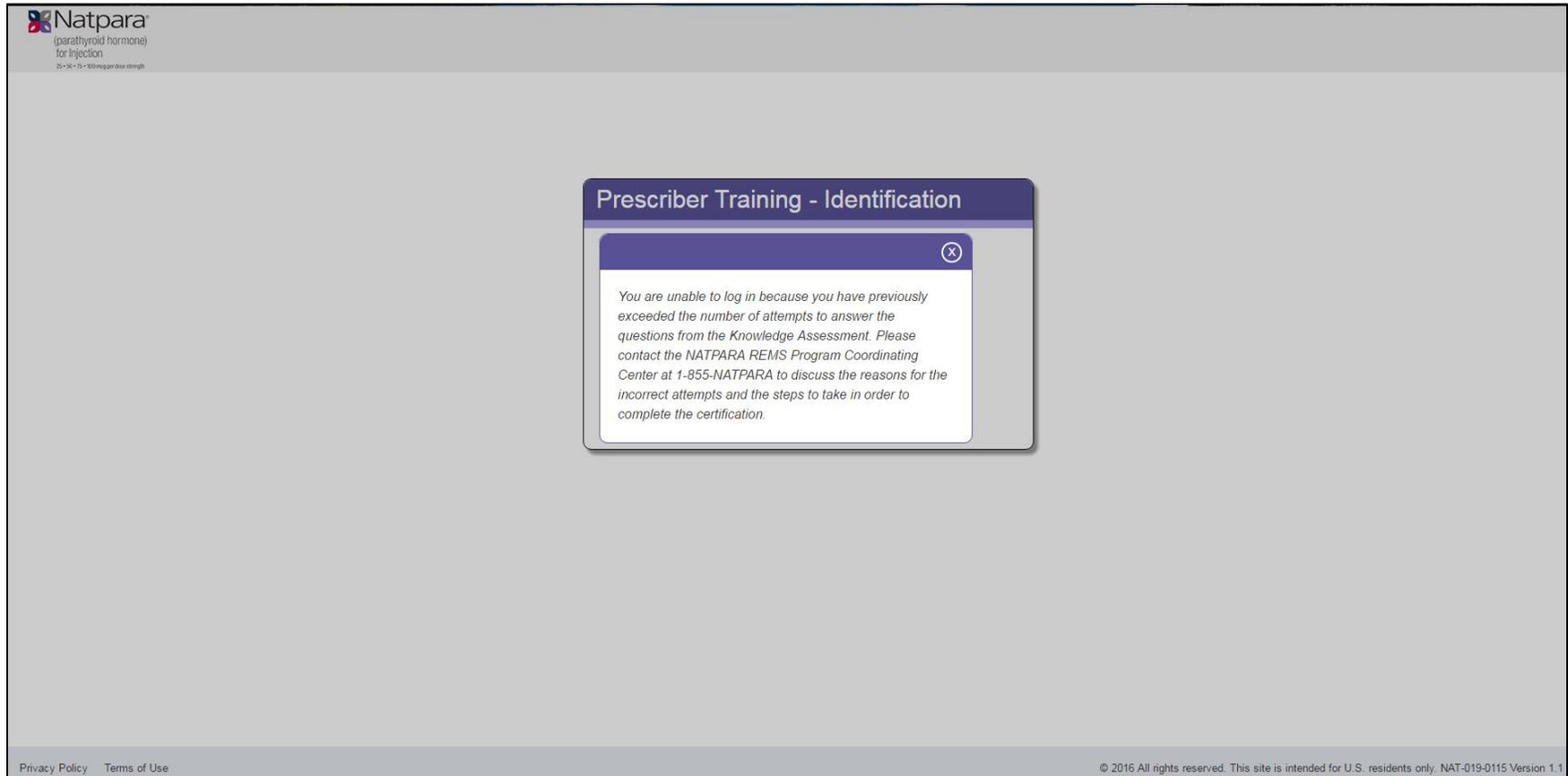
The screenshot displays the NATPARA REMS Program online prescriber certification interface. At the top left is the Natpara logo (parathyroid hormone for injection) and at the top right is a progress bar with five stages: Introduction, Training, Assessment, Enrollment, and Certify. The current stage is 'Question 3'. The question text is: 'NATPARA causes an increase in the incidence of osteosarcoma in rats'. Below the question are two radio button options: 'True' and 'False', with 'False' selected. A purple pop-up message box titled 'Exceeded Attempts' is overlaid on the question area, 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 are links for 'Privacy Policy' and 'Terms of Use', and 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'.

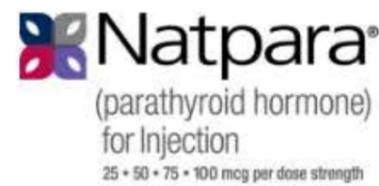
NATPARA REMS Program – Online Prescriber Certification Screen Captures (ALL)

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.





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](#)

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