

Provision of denosumab (Prolia®) treatment for patients with post-menopausal osteoporosis during the COVID-19 pandemic

COVID-19 DOCUMENT

CATEGORY:	Protocol
CLASSIFICATION:	Clinical
PURPOSE	This protocol outlines the process of providing Prolia® treatment for patients with post-menopausal osteoporosis during the COVID-19 pandemic
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Approved By:	Medical Scientific Advisory Group (COVID-19)
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Distribution:	<ul style="list-style-type: none"> • Recommended Reading for: <ul style="list-style-type: none"> • Essential reading for: All clinicians involved in the care and management of patients with osteoporosis. • Information for: all medical, nursing clinicians, as well as pharmacists. • Information for:

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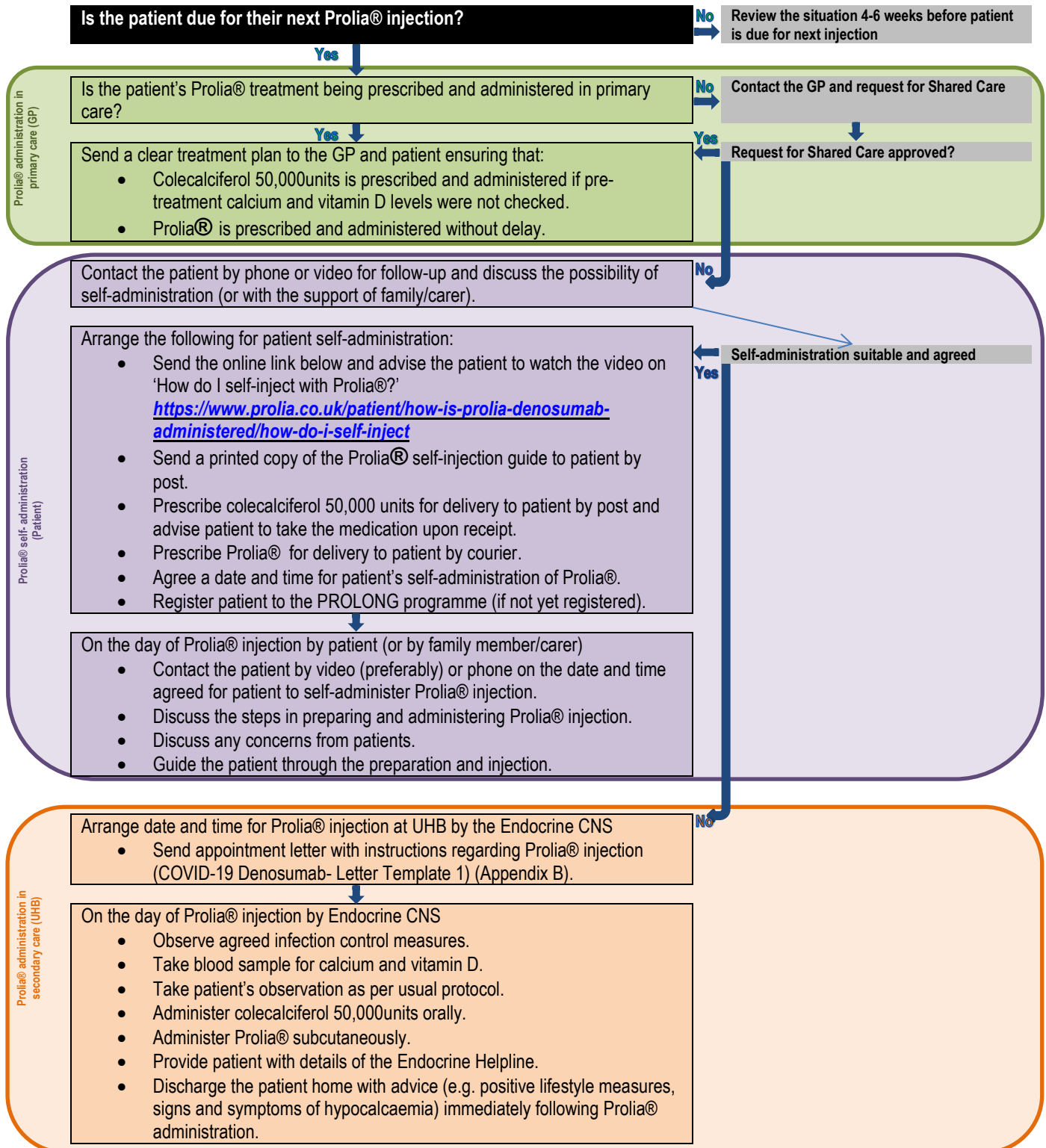
I. Overview

- 1.1 This protocol outlines the process required to ensure that the provision of denosumab (Prolia®) treatment for patients with post-menopausal osteoporosis continues during the COVID-19 pandemic.
- 1.2 The purpose of this protocol is to ensure the safety of patients receiving 6-monthly denosumab (Prolia®) injection as part of their osteoporosis treatment, whilst protecting them and our staff from COVID-19 infection. It also enables services to make the best use of NHS resources.
- 1.3 The need for patients to continue with their denosumab (Prolia®) injection during the COVID-19 pandemic has been highlighted in the published NICE guideline (<https://www.nice.org.uk/guidance/ng167>). Therefore, patients who are established on Prolia® treatment should continue with their 6-monthly injection without interruption or delay.
- 1.4 This protocol should be read in conjunction with the following local and national guidelines:
 - Effective Shared Care Agreement (ESCA): Densomab (Prolia®). Birmingham, Sandwell, Solihull and environs Area Prescribing Committee (<http://www.birminghamandsurroundsformulary.nhs.uk/docs/esca/BSSE%20APC%20ESCA%20Denosumab.pdf?uid=782173289&uid2=20158211410285&UNLID=9534928622020528105228>).
 - COVID-19 Rapid Guideline: Rheumatological autoimmune, inflammatory and metabolic bone disorders. National Institute for Health and Care Excellence. NICE Guideline [NG167] (<https://www.nice.org.uk/guidance/ng167>).

II. General Considerations

- 2.1 New patients started on Prolia® treatment should have a detailed discussion about the potential side effects from the treatment including mild upper respiratory tract infection (<https://www.medicines.org.uk/emc/product/568/smpc>). Alternative anti-fracture treatment such as oral bisphosphonate should be considered as the first choice provided that there is no contra-indication (Gittoes *et al*, 2020).
- 2.2 If pre-treatment blood testing for serum calcium and vitamin D is not possible, an empirical dose of oral colecalciferol 50,000units should be administered on the same day of patients' Prolia® injection.

III. Protocol: Provision of denosumab (Prolia®) treatment during the COVID-19 pandemic



IV. Contact Details

<u>Prof. Neil Gittoes</u> Clinical Lead, Metabolic Bone Service (Consultant Endocrinologist, QEHB)	Contact via switchboard
<u>Consultant Endocrinologist, BHH</u>	Contact via switchboard 0121-424-2000
<u>Specialist Registrar</u> Endocrinology	Contact via switchboard 0121-627-2000 (QEHB) 0121-424-2000 (BHH)
<u>Sherwin Criseno</u> Lead Nurse- Endocrinology	0121-371-6950 EndocrineNursesQEHB@uhb.nhs.uk
<u>Movianto</u> (for ordering Prolia®)	orders.uk@movianto.com Tel: 01234 248500 Fax: 01234 248705 Orders can be placed between 08:30 – 16:30, Monday to Friday.
<u>PROLONG Nurse Helpline</u>	prolong.support@nhs.net

V. References

- AMGEN (2020) How do I self-inject with Prolia®?. [Online]. Available at: <https://www.prolia.co.uk/patient/how-is-prolia-denosumab-administered/how-do-i-self-inject>.
- Birmingham, Sandwell, Solihull and environs APC Formulary. Effective Shared Care Agreement (ESCA): Denosumab (Prolia). [Online]. Available at: <http://www.birminghamandsurroundsformulary.nhs.uk/docs/esca/BSSE%20APC%20ESCA%20Denosumab.pdf?uid=782173289&uid2=20158211410285&UNLID=953492862202052811924>.
- Gittoes *et. al.* (2020) Endocrinology in the Time of COVID-19: Management of Calcium Disorder and Osteoporosis. European Journal of Endocrinology. [Online]. Available at: <https://pubmed.ncbi.nlm.nih.gov/32396134/>.
- NICE (2020) COVID-19 Rapid Guideline: rheumatological autoimmune, inflammatory and metabolic bone disorders. National Institute for Health and Care Excellence. NICE Guideline [NG167]. [Online]. Available at: www.nice.org.uk/guidance/ng167.
- Prolia: Summary of Product Characteristics. [Online]. Available at: <https://www.medicines.org.uk/emc/product/568/smpc>.

VI. Appendix A: Prolia® Self-Administration Guide

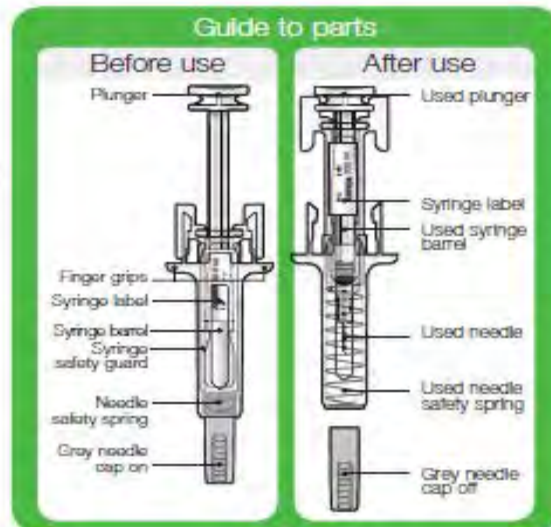
Automatic Needle Guard (ANG) Pre-filled Syringe Training Guide

Introduction

This ANG pre-filled syringe is used like a conventional syringe. Administer the medication by pushing the plunger all the way down. After delivering the full injection, a needle guard is automatically activated as you release pressure from the plunger, safely covering the injection needle. The ANG pre-filled syringe is disposed of as you would a conventional syringe.

Before you start

- Ensure that you have read the package leaflet instructions provided with this product before use
- For a more comfortable injection, leave the pre-filled syringe at room temperature for about 30 minutes before injecting
- Based upon the package leaflet instructions, select and prepare an appropriate injection site



ADMINISTER INJECTION & DEPLOY NEEDLE GUARD

Remove grey needle cover.

A Pinch the injection site to create a firm surface.

I It is important to keep skin pinched when injecting.

Hold the pinch. INSERT needle into skin.

B PUSH plunger with slow and constant pressure until you feel or hear a "snap". Push all the way down through the snap.

I It's important to push down through the "snap" to deliver the full dose.

C RELEASE your thumb. Then LIFT syringe off skin.

After releasing the plunger, the pre-filled syringe safety guard will safely cover the injection needle.



Discard used pre-filled syringe and other supplies in a sharps disposal container.



AMGEN

prolia
denosumab

Appendix B: Letter Template 1 (Continuation of Prolia® Injection During The COVID-19 Pandemic [Hospital Administration])

Dear Patient:

Continuation of Prolia® Injection During The COVID-19 Pandemic (Hospital Administration)

As you are aware, you are soon due for your next denosumab injection. It is important that you continue with your 6-monthly injection without delay. Please read the information below and contact our Endocrine Helpline by email (EndocrineNursesQEHB@uhb.nhs.uk) or by phone (0121-371-6950) should you require any further information.

Keeping you safe whilst continuing your Prolia® treatment

1. You will not be required to have a blood test prior to your injection. Instead, we will give you a single dose of vitamin D on the day of your injection.
2. The healthcare professional(s) you will be seeing in clinic will be well and very unlikely to have coronavirus. They will observe strict hand washing between patients, don a new apron and gloves for each patient and will be wearing face covering.
3. The clinic room will have been deep cleaned before the start of the clinic.
4. We will use anti-viral wipes on the door handle and chair if used between each patient.
5. Your appointment will be limited to the shortest time possible to enable safe administration of your Prolia® injection.
6. Please report to the Outpatient Department at the precise time of their appointment.
7. Please wear loose fitting clothes to ensure that you can expose your abdomen easily and quickly for the Prolia® injection.
8. Children are not allowed to accompany you to your appointment.
9. Any friend or relative who are considered high risk, extremely vulnerable or those with symptoms suggestive of coronavirus infection should not accompany you to your appointment.
10. Please continue to observe the Government's advice on regular handwashing and wearing face covering. Hand sanitizer gel will be available on the main entrance of our Outpatient Department. You must use the gel on entering and leaving the building.
11. If you have symptoms suggestive of coronavirus infection (fever or cough), you must not attend your appointment and contact us by email or phone to reschedule your appointment.
12. If you do not wish to receive your Prolia® injection at this time, please contact us by email or phone so we can discuss this further with you.

NOTE: Important information about Denosumab (Prolia®) treatment:

1. Denosumab has a quick on and off effect. It is important that it is given without delay on a 6-monthly basis.
2. Osteonecrosis of the jaw is a rare complication of Prolia® treatment. Please ensure that you maintain good oral hygiene and continue to see your dentist regularly. If you require dental treatment, this should be completed before having your next Prolia® injection.
3. Osteonecrosis of the auditory canal is also a rare complication of Prolia® treatment. Please inform us if you are suffering from ear pain, discharge from the ear, or an ear infection.
4. If you are experiencing any **new** thigh, hip or groin pain that doesn't improve after

2 weeks, please contact your GP or our Endocrine Helpline as you might need an X-ray to check for any fracture.

Your next Prolia® injection has been arranged as detailed below.

Date	
Time	
Place	Endocrine Day Case Unit Outpatient Area 1A Queen Elizabeth Hospital Birmingham Mindelsohn Way Edgbaston, Birmingham B15 2GW

Please do not hesitate to contact us by email (EndocrineNursesQEHB@uhb.nhs.uk) (preferred option) or by phone (0121-371-6950). Due to the high volume of calls we are receiving daily, it could take up to 7 days for us to get back to you.