NHS
Greater Glasgow and Clyde

CLINICAL GUIDELINE

Initiation of Foslevodopa-foscarbidopa (Produodopa) for people living with advanced Parkinson's disease

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

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Important Note:

The Intranet version of this document is the only version that is maintained.
Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

Greater Glasgow and Clyde Parkinson's Excellence Managed Clinical Network (MCN) Guidance on Initiation of Foslevodopa-foscarbidopa (Produodopa®)

Introduction/ Aim of Guideline

Produodopa® is a subcutaneous infused levodopa-based therapy. The Scottish Medicines Consortium approved Produodopa® for restricted use for adults within NHS Scotland in February 2024. Their review states that the drug can be used for "*treatment of levodopa-responsive advanced Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available combinations of Parkinson's medicinal products have not given satisfactory results."* The SMC have restricted the use of Produodopa® to patients unsuitable for deep brain stimulation (DBS).

With these indications and restrictions in mind, the Parkinson's excellence MCN have developed the following initiation guideline.

Scope

This guideline is intended for use within NHS Greater Glasgow and Clyde. Produodopa® should only be prescribed and stopped by a Parkinson's disease specialist. It is the responsibility of the clinician initiating the prescription of Produodopa, to ensure ongoing monitoring of its use.

Roles/ Responsibilities

It is good practice for the Parkinson's team to present the clinical background of the person living with Parkinson's disease, who might benefit from Produodopa®, at the bimonthly NHS GGC multidisciplinary complex case review meeting. Both the Duodopa® and DBS teams will join the discussion to ensure we meet the restrictions placed by the SMC in considering existing advanced therapies.

The DBS team will also consider direct discussion via email contact, out with the complex case review meeting but do not anticipate that all patients need to be discussed with them (such as those with clear contraindications for DBS).

The Parkinson's teams have responsibility for the following

- To ensure that candidates are suitable for treatment with Produodopa® according to SMC guidelines
- To ensure that team are adequately trained in the initiation and maintenance of Produodopa®. Training can be provided by Abbvie®.
- Provide training for the person with Parkinson's, or suitable carer, on how to use the pump
- To provide ongoing prescription, monitoring and review
- To ensure the person with Parkinson's, or carer, is familiar with the rescue pack of oral medications to start if the Produodopa® pump fails
- To ensure that movement disorder clinical documents highlight the Produodopa prescription, as well as rescue medication in event of pump failure. This information will also be added to a person's Emergency Care Summary

Guideline

The person living with Parkinson's disease should fulfil the following inclusion criteria.

- Diagnosis of idiopathic Parkinson's disease

- Disease duration >5 years
- Inadequately controlled by oral levodopa medications
- Person has capacity for informed consent
- 5-2-1 rule satisfied:
  - (taking >5 doses of levodopa/day) OR
  - Having OFF symptoms >2 hours of waking day OR
  - Having >1 hour of troublesome dyskinesia per waking day
- Further reasonable drug therapeutic options are unlikely to benefit or contraindicated
- Unsuitable, refused or failed DBS
- Can already have DBS in situ but no longer managing symptoms

Contraindications

For full information of contraindications and cautions, please refer to *Summary of Product Characteristics (SPC) for full information or Stockley's Drug Interactions at* https://www.medicinescomplete.com/#/interactions/stockley

- Non-selective monoamine oxidase (MAO) inhibitors and selective MAO type A inhibitors are contraindicated for use with Produodopa® and they must be discontinued at least 2 weeks prior to initiating therapy with Produodopa®

Cautions

- Lack of social support
- History of severe peripheral neuropathy
- Caution in low body weight
- Caution with diabetes mellitus (higher risk of skin problems)
- Caution with local skin problem (eczema, psoriasis, open areas, neuropathy)
- Caution with anticoagulant use, risk of bruising, haematoma affecting medication absorption
- End of life/ palliative stages – consider may be suitable to continue to run but not to start
- Active malignant or active treatment
- Malignant melanoma
- Active psychosis

Please note this list is not exhaustive. Refer to Summary of Product Characteristics (SPC) for full information

Equipment

Delivery system includes- Vyafuser® pump and single use infusion components including syringe, syringe infusion set, solution vial and vial adapter

Only the Vyafuser® pump should be used for administration of Produodopa®

Before date of initiation

Review skin to ensure intact.

Baseline – consider UPDRS III, NMS, MOCA, Epworth Sleepiness Scale, PDQ – 39.

In all, check bloods – FBC, UE, LFT, HbA1ct, Vit B12 and B6, Folate, Weight, BMI, BP sitting and standing.

Order medications/ pump.

Arrange date to start outpatient or inpatient.

Decide with patient before attendance whether to attend in OFF state or ON state, this practice will vary according to unit. Convert COMT and current levodopa containing medicines to levodopa equivalents, LE (see dosing and administration guidance for calculation)

Maintain MAO-b and dopamine agonists. See links below to dose conversion guides.

Initiation

Determine the initial hourly infusion rate based on calculated LE (see table in dosing and administration link) This rate should be entered as the base infusion rate when programming the pump.
Stop oral COMT/ levodopa. Continue MAO-B and dopamine agonists.

The following links give instruction as to how to set up the pump, how to calculate the levodopa equivalents dose, the hourly infusion rate and the volume of a loading dose which can be administered when starting Produodopa® in an "off" state or if the pump has been off for more than 3 hours.

UK - Produodopa Patient Video (brightcove.net)
Dosing and Administration (abbviepro.com)
Produodopa 240 mg/ml + 12 mg/ml solution for infusion - Risk Management Materials - (emc) | 15213

Initiation as out-patient will require between one to six visits dependent on patient need on week 1. These sessions will include;

Education for patient/carer on pump/ skin care etc

Education patient/carer/GP on rescue pack of medications if pump failure.

Monitoring to see if requirement for reduction in dose of Parkinson's medications (either pump or oral/patch).

Dose titration of Produodopa®

Follow-up after initiation of infusion

Day 1 - telephone check

By end of week 1 - face to face review to include assessment of skin integrity. This will be carried out by a qualified nurse funded by the manufacturers to support safe delivery of treatment at home

By end of week 2 - titration of medication by hospital based Parkinson's team

2 months - titration of medication by hospital based Parkinson's team

6 months at usual planned follow up with Parkinson's team, check B12, B6 and Folate.

Consider stopping pump if;

- intolerable side effects (such as repeated skin infections/ breakdown).
- Lack of social support for maintaining pump.
- Lack of clinical benefit as determined by Parkinson's team. This would require restarting oral medications and should not be done without input from Parkinson's specialist.

Ongoing prescriptions will remain the responsibility of the patient's Parkinson's team.

Prescriptions should be sent both electronically and in hard copy to:

NHSGGC Homecare Team
Pharmacy Distribution Centre
10 Dava Street
Moorpark Central
Govan
G51 2BQ
Telephone No : 0141-347-8974

Email: *GGC.Homecareservices@nhs.scot*

Please note separate NHS GGC guideline; Produodopa® continuation while in patient

References

foslevodopa foscarbidopa (Produodopa) (scottishmedicines.org.uk)

Produodopa 240 mg/ml + 12 mg/ml solution for infusion - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)