NHS
Northamptonshire
Clinical Commissioning Group

Commissioning Policy for Co- careldopa intestinal gel (Duodopa®)for advanced Parkinson's disease

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POLICY

NHS Northamptonshire has reviewed the evidence for Co-careldopa intestinal gel (Duodopa®) in the management of advanced Parkinson's disease and consider its use to be a LOW PRIORITY due to lack of evidence of clinical and cost effectiveness.

STATUS

Mandatory

RATIONALE

The pivotal trial for use of Duodopa®, the DIREQT was limited to 24 patients who had received only three weeks of co-careldopa intestinal gel monotherapy (the first week of which was a dose adjustment period) via naso-duodenal tube. The gel requires administration via a surgically implanted trans-abdominal tube when used long term. Given that the SPC notes that complications with the device are very common (greater than one in ten), the short term DIREQT trial in which co-careldopa intestinal gel was administered via naso-duodenal rather than trans-abdominal tube, provides limited information in relation to safety, patient experience and quality of life with usual long-term use of this product. There is a lack of long-term follow up data on which to base the economic modelling for Duodopa®. The estimates of effectiveness used in the model are based on hypothetical health states, created from short-term comparative efficacy data relating to a narrow section of the PD patient population.

EVIDENCE

1. Parkinson's disease (PD) is a progressive, neurodegenerative condition that is estimated to affect 100–180 people per 100,000 of the population and has an annual incidence of 4–20 per 100,000.
2. Duodopa® is indicated for the treatment of advanced levodopa responsive Parkinson's disease with severe motor fluctuations and dyskinesia.
3. For long-term administration, the gel should be administered directly into the proximal jejunum via a permanent percutaneous endoscopic gastrostomy (PEG) tube
4. The DIREQT study is the main clinical trial to compare the safety and efficacy of Duodopa® with conventional treatment. In this single blinded, cross over study, 24 patients were randomised to receive conventional treatment for three weeks and intra-duodenal administration of Duodopa® for three weeks. Moderate to severe off state was reduced significantly in all patients during treatment with infusion. Moderate to severe dyskinesia was uncommon. Additionally the UPDRS, PDQ39 and electronic diary parameters documenting quality of life showed improvement during treatment with Duodopa®.

5. The estimated annual cost of treatment is £28,000, this excludes the cost of 4 follow up neurology appointments in the first year.

IMPLICATIONS FOR EQUALITY AND DIVERSITY

[Race, Disability, Gender, Religion and Belief, Sexual orientation, age]

Low Implication

FUTURE ACTION

- Equal Opportunities monitoring to assess number of requests received.
- Annual review to include analysis of equal opportunities data compare to local demographics and user groups
- Under or over representation information to be presented to Information Governance

PROCESS FOR INDIVIDUAL FUNDING REQUEST

Individual funding requests should be made to the CCG using the appropriate form which is available here

All requests should be sent to the IFR/Prior approval team. E-mail correspondence will be processed quicker. All e-mail correspondence will need to be sent to the following address:
Ifr.northants@nhs.net.