NHS
Greater Glasgow and Clyde

CLINICAL GUIDELINE

Teduglutide for Short Bowel Syndrome in Adults, Assessment and Monitoring

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.

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AIM / OBJECTIVE OF GUIDELINE

This clinical guideline will outline evidence-based recommendations for use when prescribing Teduglutide for Short Bowel Syndrome (SBS) in adults.

It will also provide advice for the initial assessment and ongoing monitoring of patients receiving Teduglutide.

Teduglutide may only be prescribed by a Consultant within the NHSGGC Intestinal Failure Team (IFT), based at GRI with experience in the management of patients with established SBS.

INTRODUCTION / BACKGROUND

Teduglutide was accepted for use in Scotland for the treatment of SBS, in children in 2018 and extended to adults in January 2020 (1).

Short bowel syndrome is described as intestinal malabsorption, which is associated with a functional small intestine length of less than 200 cm (2). Clinical management of SBS currently aims to maximize available intestinal function by managing oral fluids, dietary modification and the use of anti-secretory / anti-motility medications. Supplementary fluids, macro and micro nutrients are given as required to maintain health via Parenteral Supplementation (PS) (3).

The intestinal mucosa lining the intestine ensures that the body is protected from undesirable bowel content while ensuring the absorption of nutrients. Maintenance, growth and repair of the intestinal mucosa are dependent on many factors. Peptide hormones, including glucagon like peptide-2 (GLP2), can reduce secretions and gastric motility as well as stimulate mucosal growth (3).

Teduglutide is a GLP2 analogue which has been shown in trials to promote and repair the mucosal layer of the intestine by increasing the height of villus and depth of crypts (1).

It is given once daily following reconstitution as a subcutaneous injection of 0.05mg/kg.

NHSGGC Formulary highlights that Teduglutide is restricted for prescribing to the IFT for patients with SBS after all other treatments have been optimized. Patients must be stable on PS for at least 2 years and success of Teduglutide is measured in the reduction of PS. (4)

SCOPE

This clinical guideline is for the use of NHSGGC IFT members with direct management of patients with established SBS who require Home PS.

ROLES / RESPONSIBILITIES

Consultant – Initial patient assessment, education and gain consent. Request pre-assessment screening and review. Teduglutide prescription.

Pharmacy – Pharmaceutical reconciliation. Liaise with Homecare Company / Pharmacy Homecare office regarding prescription. Clinically screen prescription.

Nutrition Nurse – Complete registration with Homecare Company. Arrange injection training. Clinic review.

Dietician – Ongoing nutritional assessment.

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Eligibility Criteria:

1) Stable on Home Parental Nutrition (HPN) for >2 years, and
2) Surgical reinstatement of continuity has been performed if possible, and
3) Patient with the prospect to reduce or stop HPN.

NHS Health Board Notification:

1) General Manager / Clinical Service Manager for Surgery & Anesthetics to be informed prior to NHSGGC referrals commencing treatment.
2) Health Boards outside of NHSGGC to be informed prior to commencement of treatment if patient residences outside of NHSGGC.

Pre-assessment:

1) If colon is present - colonoscopy to detect and remove polyps.
2) OesophagoGastroDuodenoscopy.
3) Baseline CT thorax, abdomen and pelvis, before or within 3 months of starting treatment.
4) Baseline micronutrient screen.
5) Complete Pre-Assessment documentation.
6) Calculate Teduglutide dose.
7) Gain verbal consent ensuring understanding of Teduglutide continuation goal and reasons for termination of treatment, including malignancy, obstruction, continuation goal not achieved and noncompliance.

Ongoing monitoring:

1) Nutrition clinic review at week 2 and week 4. Including weight and bloods. Then monthly for 3 months.
2) Reduce to quarterly monitoring when stable for 1 year then reduce to standard follow up.
3) Dose to be decided during clinic visit, clearly documented and communicated.
4) Week 24 review of efficacy with prescribing consultant.
5) Twice yearly efficacy review within clinic by IFT.
6) Once yearly colonoscopy and oesophagogastroduodenoscopy or alternative imaging are recommended during the first 2 years then at five year intervals.

Confirmation of response:

1) Assessed by Consultant.
2) Meet criteria set out at pre-assessment on an individual basis.
3) 20% reduction in PS use minimal expected.
4) If individual pre-assessment criteria are not met Teduglutide will be stopped.

Injection details:

Once daily subcutaneous injection at 0.05mg/kg of body weight using a 5mg vial.
Store below 25 degrees C.
Do not freeze.

White powder mixed with solvent into a 0.5ml solution.
The vial should not be shaken, can be rolled and turned upside down once.
Should be used immediately however, can be stored at room temperature for up to 3 hours.
Inject into the abdomen or if not possible the thigh. (5)

Following reconstitution the following volume is given;

Body weight	5 mg strength Volume to be injected
38-41 kg	0.20 ml
42-45 kg	0.22 ml
46-49 kg	0.24 ml
50-53 kg	0.26 ml
54-57 kg	0.28 ml
58-61 kg	0.30 ml
62-65 kg	0.32 ml
66-69 kg	0.34 ml
70-73 kg	0.36 ml
74-77 kg	0.38 ml

78-81 kg	0.40 ml
82-85 kg	0.42 ml
86-89 kg	0.44 ml
90-93 kg	0.46 ml

Contraindications:
(See Summary of Product Characteristics for further details)

Hypersensitivity to the active substance or to any of the excipients or trace residues of tetracycline.
Active or suspected malignancy.
Patients with a history of gastrointestinal malignancy in the last 5 years. (5)

Special warnings and precautions for use:
(See Summary of Product Characteristics for further details)

Colo-rectal polyps
Gastrointestinal neoplasia including hepatobiliary tract
Gallbladder and bile ducts
Pancreatic diseases
Monitoring of small bowel, gallbladder and bile ducts and pancreas
Intestinal obstruction
Concomitant medicinal products (narrow therapeutic index)
Fluid overload and Electrolyte balance – most frequently noted in first 4 weeks of treatment (5)

Injection Site Reactions:

26% of patients can expect to experience a moderate injection site reaction including – haematoma / erythema / pain / swelling / haemorrhage. (5) Ensure good use of site rotation.

REFERENCES

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