HERPC

Hull & East Riding Prescribing Committee

Prescribing Framework for Sandostatin analogues for management of high output stomas (off label use of licensed medicine)

Patient's Name:……..… NHS Number: ……

Patient's Address:……...……(Use addressograph sticker)

GP's Name:……..

Communication

We agree to treat this patient within this Prescribing Framework
Specialist Prescriber's Name…… Prof Reg. No. ……
Specialist Prescriber's Signature…… Date:……
Where prescriber is not a consultant:
Consultant's Name: …… GMC No ……..
Consultant's Signature ……... ……. Date:…….
GP's Signature:…… Date:……..
GP's Name (if different from listed above)……..

The front page of this form should be completed by the specialist and the form sent to the patient's general practitioner.
The patient's GP should sign and send back to specialist, to confirm agreement to enter into shared care arrangement. If the General Practitioner is **unwilling** to accept prescribing responsibility for the above patient the specialist should be informed within two weeks of receipt of this framework and specialist's letter.

Full copy of framework can also be found at : http://www.hey.nhs.uk/amber.htm

1. Background

There are many possible causes of high output stoma including infection and bacterial overgrowth, bowel obstruction, recurrent bowel disease, medicines use. Patients require assessment by specialist for assessment and acute treatment. Though corrective measures may “stop” some of the causes, many patients will require on-going treatment for symptom control and to prevent dehydration.

In its native form octreotide is an octapeptide analogue of somatostatin administered by subcutaneous injection. Biological response is maintained for at least 8 hours following injection. A high percentage of patients currently prescribed subcutaneous octreotide find three injections unacceptable contributing to poor compliance (up to 50% of patients) with the additional problem that hormonal control escape may occur overnight. Octreotide can reduce stoma output by 1-2 L/24 hrs. It can be trialled if antisecretory drugs such as H2 antagonists and PPIs fail. Following a successful trial and if long term therapy is required long acting preparations will be requested to aid compliance.

A trial of 2-3 days of subcutaneous octreotide 50 micrograms twice daily may be recommended. Treatment will be stopped after 72 hours if there is no noticeable reduction in output. If improvement is seen, the dose can be titrated gradually up to a maximum of 100micrograms three times each day. This will be prescribed and monitored by specialist.

This document should be read in conjunction with the guidance “Responsibility for prescribing between Primary & Secondary/Tertiary Care” https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf

2. Indication

Reduction of stoma output in patients with high output stoma. This is an unlicensed indication using a licensed product.

3. Dose

	Sandostatin LAR /Olatuton	**Somatuline LA**	**Somatuline Autogel**
Drug	**Octreotide**	**Lanreotide**	**Lanreotide**
Strengths available	10, 20 and 30 mg	30 mg	60, 90 and 120 mg
Formulation	Powder and solvent for suspension for injection (Follow manufacturers reconstitution instructions)	Powder for suspension for injection. (Follow manufacturers reconstitution instructions)	Prefilled syringe, ready for administration.
Route of administration	Deep intragluteal injection (repeated injections should be alternated between the left and right gluteal muscle)	Intramuscular injection	Deep subcutaneous Injection into superior external quadrant of the buttock or in the upper outer thigh.

Initial dose	20 mg every 4 weeks for 3 months.	30 mg every 14 days	60 mg every 28 days. Patients previously initiated on Somatuline LA may be converted to 60, 90 or 120mg of Somatuline Autogel every 28 days. This decision would be made by the hospital specialist.
Dose adjustment based on clinical symptoms	Initially adjust dose (e.g. by 10 mg every 4 weeks) up to 30 mg every 4 weeks	Adjust frequency (30 mg every 7 to 10 days)	Adjust dose up to 120 mg every 28 days

4. Duration of treatment

As per specialist

5. Contraindications and cautions

Somatostatin analogues may reduce gall bladder motility, bile acid secretion and bile flow, and there is an acknowledged association with the development of gallstones. If patients develop symptoms suggestive of gallstones they should be investigated in the normal way. If gallstones are confirmed refer to specialist to discuss risk/benefits of continuing therapy.

Somatostatin analogues inhibit the secretion of insulin, glucagon and growth hormone. Patients with diabetes may experience a slight transient alteration of blood glucose levels. Their diabetes control should be monitored as normal and changes in therapy instituted if necessary. Non diabetics will have a random blood glucose checked after the first depot injection prior to handover to primary care and an annual HbA1c in primary care.

6. Adverse effects

Octreotide inhibits many gastrointestinal functions. The commonest side effects are thus steatorrheoa due to inhibition of pancreatic enzyme secretion and gallstone formation due to biliary stasis; gallstones are a potential contra-indication to use of the drug. Steatorrheoa may be overcome by the use of pancreatic enzyme supplements.

Due to its inhibitory action on growth hormone, glucagons and insulin release, octreotide may affect glucose regulation. Post prandial glucose tolerance may be impaired. In some instances a state of persistent hyperglycaemia and diabetes mellitus may be induced as a result of chronic administration. Hypoglycaemia has also been observed.
In patients with concomitant Type I diabetes mellitus, Sandostatin LAR is likely to affect glucose regulation, and insulin requirements may be reduced.

7. Interactions

Octreotide has been found to reduce the intestinal absorption of ciclosporin. Also, it is reported that concomitant administration of lanreotide injection with ciclosporin may also decrease blood levels of ciclosporin.

Patients on ciclosporin who are started on octreotide or lanreotide may need their ciclosporin levels monitoring and may need their dose adjusting by the specialist responsible for ciclosporin.

Details of contraindications, cautions, drug interactions and adverse effects listed above are not exhaustive. For further information always check with BNF www.bnf.org.uk or SPC (www.medicines.org.uk).

8. Monitoring

Routine disease monitoring should continue. No additional monitoring specific to the drug to be undertaken by the GP.

9. Information to patient

Patients will be educated as to the condition of which they suffer and advised about symptoms and side effects of Octreotide depot treatments

10. Responsibilities of clinicians involved

Stage of Treatment	Specialist	General Practitioner
Initiation	Diagnosis of condition and ensuring other treatment options have been fully explored and agreed with the patient Administer the first long acting depot injection and check random blood glucose after for non-diabetic patients Checking for allergies, interactions and contra-indications To initiate treatment, administration by nurse Communicate with GP regarding diagnosis, drug name (including brand name), strength and frequency. Advising GP on dose to be prescribed and titration schedule if appropriate.	
Maintenance	Outlining to the GP when therapy may be reduced and stopped assuming no relapse in patient's condition. Review periods and follow up arrangements to be agreed Responding to issues raised by GP Train patient/carer on administration,	Checking for allergies, interactions and contra-indications when taking over prescribing and when changing any other medication Prescribing the amber medicine after receiving request from the specialist Prescribe medication by brand name as

	where the patient wishes to self/carer administer (Lanreotide Autogel only). Provide support materials and training where needed on administration to GP Practice Nurses/Nurse Practioners. Offer patient the option of homecare delivery service and/or ongoing administration of therapy with the homecare service nursing team. Advise GP on need for pancreatic enzyme supplements.	instructed by specialist. Prescribe pancreatic enzyme supplements, if advised by consultant Arrange for treatment to be administered Monitoring the patient's overall health and wellbeing, observing patient for evidence of ADRs and liaising with the specialist if necessary. Routine disease monitoring should continue as per high output stoma guideline. Ensuring advice is sought from the specialist if there is any significant change in the patient's physical health status that may affect prescribing or appropriateness of the amber medicine Reducing/stopping treatment in line with the specialist's request To organise an HbA1c level every 12 months in patients without diabetes mellitus.

Contact Details:

During Office hours: Consultant gastroenterologist as per clinic letter
Out of hours: Gastroenterology registrar oncall via switch board

Philippa Macelhinney Hull University Teaching Hospitals NHS Trust
(Specialist nurse – nutrition team) 01482 622131

Anita Middleton Hull University Teaching Hospitals NHS Trust
(Specialist nurse – nutrition team) 01482 622131

Specialist Pharmacist: Sharn Day – Advanced Specialist Pharmacist – Nutrition and Intensive Care - **01482 624104**

APPROVAL PROCESS

Written by:	***Jane Morgan, Interface Pharmacist***
Consultation process:	***Dr Smithson, Dr Nelson – Consultant Gastroenterologists. Sarah Westerhold – Principal Pharmacist, Sharn Day – Advanced Clinical Pharmacist***
Approved by:	***MMIG***
Ratified by:	***HERPC***
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