BC Cancer Protocol Summary for Symptomatic Management of Functional Carcinoid and Neuroendocrine Tumors of the GI Tract Using Lanreotide (SOMATULINE AUTOGEL)

Protocol Code  UGILAN

Tumour Group  Gastrointestinal

Contact Physician  GI Systemic Therapy

ELIGIBILITY:
- Functional neuroendocrine tumors of the mid-gut or pancreas (including carcinoid tumors and VIPoma), with symptoms due to ectopic hormone secretion (flushes, diarrhea, wheezing, etc.)
- A BC Cancer Compassionate Access Program (CAP) request with appropriate clinical information for each patient must be approved prior to treatment. CAP approval is valid as long as patient has symptomatic benefits.

EXCLUSIONS:
- Pregnant or lactating women
- Hypersensitivity to lanreotide, somatostatin, or related peptides (such as octreotide)
- Complicated, untreated lithiasis of the bile ducts

TESTS:
- Pretreatment ultrasound of the gall bladder is recommended to rule out the formation of gallstones. Repeat periodically or if symptoms suggestive of biliary colic occur while on therapy.
- Blood glucose is recommended prior to therapy initiation and with dose changes.
- Cardiac monitoring (such as heart rate) is recommended in patients with pre-existing cardiac disorders.

PREMEDICATIONS:
- Not usually required

TREATMENT:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>BC Cancer Administration Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>lanreotide (SOMATULINE AUTOGEL)</td>
<td>120 mg**</td>
<td>Deep Subcutaneous Injection (upper outer quadrant of buttocks alternating between right and left sides*)</td>
</tr>
</tbody>
</table>

*May use upper outer thigh for self-administration

Repeat every four weeks.
DOSE MODIFICATIONS:

Hepatic Dysfunction: Has not been studied in this patient population. Other patient populations (acromegaly) have safely used a dose of 60 mg in moderate or severe hepatic impairment.

Renal Dysfunction: No dose modification required for mild to moderate renal impairment. For severe renal impairment (CrCl less than 30 mL/min), it has not been studied in this patient population. Other patient populations (acromegaly) have safely used a dose of 60 mg.

PRECAUTIONS:

1. Loss of blood glucose control can occur: either hypoglycemia or hyperglycemia. Monitor blood glucose when treatment is initiated and when dose is changed. Diabetics may need their treatments adjusted. Insulin requirements may be reduced in insulin-dependent patients.
2. Reduced gall bladder motility may occur and may lead to formation of gall stones.
3. Potential for some impairment in thyroid function: monitor for signs and symptoms of hypothyroidism.
4. Bradycardia may occur in patients with or without existing cardiac disorders. Monitor heart rate. Initiate with caution in patients with pre-existing bradycardia.

Call the GI Systemic Therapy physician in your regional cancer centre or the GI Systemic Therapy Chair Dr. Janine Davies at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.

REFERENCES:

1. SOMATULINE® AUTOGEL Product Monograph Ipsen Biopharm Limited (EMD Serono Canada) Jan 30, 2015
2. SOMATULINE® AUTOGEL Product Monograph Ipsen Biopharm Limited NJ, USA Dec 2014