Managing Acromegaly: Biochemical Control With Sandostatin® LAR Depot (octreotide acetate for injectable suspension)

**INDICATION AND USAGE**
Sandostatin® LAR Depot (octreotide acetate for injectable suspension) is indicated for long-term maintenance therapy in acromegalic patients who have had inadequate response to surgery and/or radiotherapy or for whom surgery and/or radiotherapy is not an option in patients in whom initial treatment with immediate release Sandostatin® (octreotide acetate) Injection has been shown to be effective and tolerated. The goal of treatment in acromegaly is to reduce GH and IGF-1 levels to normal.

**HIGHLIGHTS OF IMPORTANT SAFETY INFORMATION**
- Treatment with Sandostatin LAR Depot may affect gallbladder function, glucose metabolism, thyroid and cardiac function, and nutritional absorption. Periodic monitoring is recommended.

Please see additional Important Safety Information on slides 16 and 17. Please see full Prescribing Information.
Objectives

• Understand the roles of growth hormone (GH) and insulin-like growth factor 1 (IGF-1) in acromegaly
• Recognize the goal of treatment and importance of biochemical control of GH and IGF-1
• Know how the use of Sandostatin® LAR Depot (octreotide acetate for injectable suspension) after surgery can provide biochemical control
• Identify opportunities for nurses to support adequate control through counseling and interventions
Sandostatin® LAR Depot Indication

Sandostatin® LAR Depot is indicated for patients in whom initial treatment with immediate release Sandostatin® (octreotide acetate) Injection has been shown to be effective and tolerated for:

• Long-term maintenance therapy in acromegalic patients who have had inadequate response to surgery and/or radiotherapy or for whom surgery and/or radiotherapy is not an option (the goal of treatment in acromegaly is to reduce GH and IGF-1 levels to normal).

Reference
Sandostatin LAR Depot [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2011.

Please see additional Important Safety Information on slides 16 and 17. Please see full Prescribing Information.
Highlights of Important Safety Information

- **Warnings and Precautions**: Treatment with Sandostatin® LAR Depot may affect gallbladder function, glucose metabolism, thyroid and cardiac function, and nutritional absorption (periodic monitoring is recommended). Cardiac function: use with caution in at-risk patients.

- **Drug Interactions**: The following drugs require monitoring and possible dose adjustment when used with Sandostatin LAR Depot: cyclosporine, insulin, oral hypoglycemic agents, beta-blockers, and bromocriptine.

- **Adverse Reactions**: The most common adverse reactions occurring in ≥20% of patients are: diarrhea, cholelithiasis, abdominal pain, and flatulence.

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Overview of GH

- GH is produced by the pituitary gland, which is located at the base of the brain
  - GH is part of a cascade of hormones that regulates the physical growth of the body
  - The pituitary gland secretes GH into the bloodstream and travels throughout the body
- Acromegaly is a hormonal disorder caused by a benign tumor on the pituitary gland
  - In the vast majority of cases, this pituitary adenoma produces excessive amounts of GH

Reference
Overview of IGF-1

• GH stimulates the liver to produce the hormone IGF-1\(^1\)
  – IGF-1 causes tissue growth in the body
• If the tumor on the pituitary gland continues to overproduce GH, IGF-1 levels will also continue to rise\(^1\)
  – Can lead to symptoms of acromegaly, including bone overgrowth, organ enlargement, and changes in glucose and lipid metabolism
  – Complications may develop

Long-term exposure to high GH and IGF-1 levels may cause complications\(^2\)

Note: Studies conducted with Sandostatin\(^\text{®}\) LAR Depot evaluated the effects on GH and IGF-1 levels, but not on the symptoms of acromegaly.

References
Goal of Treatment: Biochemical Control

- Pituitary surgery is the primary treatment for patients with microadenomas and noninvasive macroadenomas¹
  - Normalization of IGF-1 is achieved in 75% to 95% of patients with microadenomas and in 40% to 68% of those with macroadenomas²
- If surgery fails to achieve biochemical control, medical therapy is most often used to treat acromegaly³
  - One medical therapy is Sandostatin® LAR Depot

References
Goal of Treatment: Biochemical Control (cont)

- Sandostatin® LAR Depot is used to treat patients with acromegaly who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option\(^1\)
  - Inhibits GH secretion\(^1\)
  - Effective in lowering GH levels in up to 66% of patients (47%-66%)* and IGF-1 levels in up to 67% of patients (51%-67%)
- During treatment, GH and IGF-1 should be measured to assess biochemical response\(^1\)
  - GH is measured by taking multiple random serum samples or with an oral glucose tolerance test (OGTT)\(^2\)
  - IGF-1 requires only a random blood sample

*Values are for patients achieving GH levels <2.5 ng/mL.

References

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Goal of Treatment: Biochemical Control (cont)

Definitions of control¹

<table>
<thead>
<tr>
<th>Serum GH Testing</th>
<th>OGGT GH Testing²</th>
<th>IGF-1 Testing</th>
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</thead>
<tbody>
<tr>
<td>&lt;1.0 ng/mL</td>
<td>&lt;0.4* ng/mL</td>
<td>Normalized for age and gender</td>
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*Serum GH <0.4 ng/mL has been suggested, and although current GH assays have improved sensitivity, many assays do not have sufficient accuracy at GH levels <1 ng/mL.³

References
Sandostatin® LAR Depot is a Somatostatin Analogue

INDICATION
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Highlights of Important Safety Information

• **Warnings and Precautions**: Treatment with Sandostatin® LAR Depot may affect gallbladder function, glucose metabolism, thyroid and cardiac function, and nutritional absorption (periodic monitoring is recommended). Cardiac function: use with caution in at-risk patients.

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Biochemical Control With Sandostatin® LAR Depot

Highlights of Important Safety Information

• **Warnings and Precautions**: Treatment with Sandostatin LAR Depot may affect gallbladder function, glucose metabolism, thyroid and cardiac function, and nutritional absorption (periodic monitoring is recommended).

• Cardiac function: use with caution in at-risk patients.

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The Importance of Biochemical Control in Acromegaly

• Approximately half of patients with macroadenomas are not optimally controlled with surgery alone

~50%

Reference
Nurse’s Role in Treating Patients With Acromegaly

• Reinforce with each patient the importance of adequate biochemical control
• Discuss the patient’s concerns with the extended health care team
• Encourage patient to track his or her GH and IGF-1 levels
Treating to Goal: Summary

- Acromegaly is caused by a benign tumor on the pituitary gland that leads to the excessive secretion of GH and IGF-1
- Biochemical control of GH and IGF-1 levels may be achieved with the use of Sandostatin® LAR Depot
- Nurse interaction can help patients:
  - Recognize the importance of biochemical control
  - Track their GH and IGF-1 levels
Sandostatin® LAR Depot
Important Safety Information

Warnings and Precautions:

• Gallbladder abnormalities may occur: Patients should be monitored periodically.
• Glucose Metabolism: Hypoglycemia or hyperglycemia may occur. Blood glucose levels should be monitored when Sandostatin LAR Depot treatment is initiated or when the dose is altered. Antidiabetic treatment should be adjusted accordingly.
• Thyroid Function: Hypothyroidism may occur. Baseline and periodic assessment of thyroid function (TSH, total and/or free T4) is recommended.
• Cardiac Function: Bradycardia, arrhythmia, conduction abnormalities, and other EKG changes may occur. The relationship of these events to octreotide acetate is not established because many of these patients have underlying cardiac disease. Use with caution in at-risk patients.
• Nutrition: Octreotide may alter absorption of dietary fats. Monitoring of vitamin B\textsubscript{12} levels is recommended during therapy with Sandostatin LAR Depot. Patients on total parenteral nutrition (TPN) and octreotide should have periodic monitoring of zinc levels.

Reference
Sandostatin LAR Depot [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2011.

Please see additional Important Safety Information on slide 17.
Please see full Prescribing Information.
Important Safety Information (cont)

- **Drug Interactions**: The following drugs require monitoring and possible dose adjustment when used with Sandostatin LAR Depot: cyclosporine, insulin, oral hypoglycemic agents, beta-blockers, and bromocriptine. Octreotide has been associated with alterations in nutrient absorption, so it may have an effect on absorption of orally administered drugs. Drugs mainly metabolized by CYP3A4 and which have a low therapeutic index should be used with caution.

- **Adverse Reactions**: The most common adverse reactions occurring in patients receiving Sandostatin LAR Depot were biliary abnormalities (52%), diarrhea (36-48%), cholelithiasis (13-38%), abdominal pain or discomfort (11-29%), flatulence (26%), influenza-like symptoms (20%), constipation (19%), headache (15%), anemia (15%), hyperglycemia (15%), injection site pain (2-14%), hypertension (13%), dizziness (12%), fatigue (11%), nausea (10%), vomiting (7%), hypothyroidism (2%), hypoglycemia (2%), and goiter (2%).

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