ACMA WEBINAR SESSION

The Weight Loss Craze:
Navigating Approvals & Patient Demands

Date: Feb 21st, 2024
Time: 1PM EST

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Semaglutides listed in TIME’s Best Inventions of 2023
The Semaglutide Surge

Semaglutide prescriptions increased 40-fold over the past 5 years

Share of all patients with a health care visit who were prescribed semaglutide

Note: The US Food and Drug Administration has approved three semaglutide treatments: injectables Ozempic and Wegovy, and the Rybelsus tablet. Data as of September 21, 2023.

Source: Epic Research
The Semaglutide Surge # Semaglutide patients with Type 2 diabetes decreased by > 30%

Share of patients prescribed semaglutide who have Type 2 diabetes

Note: Data as of September 21, 2023.

Source: Epic Research
GLP-1 Receptor Agonists (RAs)

- **How does it work?** biosynthetic form of the GLP-1 hormone
  - Slows rate of gastric emptying
  - Directly increases satiety – suppresses appetite in brain
  - Stimulates insulin release in pancreas & suppresses glucagon secretion

- **What are GLP-1 agonists?**
  - Semaglutide (Ozempic, Wegovy)
  - Tirzepatide (Mounjaro, Zepbound)
  - Liraglutide (Saxenda)

- **Mean weight loss difference between GLP-1 RAs* and Placebo:**
  - With diabetes = 4 - 6.2%
  - Without diabetes = 6.1 - 17%
  *% weight loss varies based on specific product

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## Popular GLP-1 Agonists Used for Weight Loss in the U.S.

<table>
<thead>
<tr>
<th>Brand Drug</th>
<th>Generic</th>
<th>Manufacturer</th>
<th>Weight Loss Approval Status (Feb 2024)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ozempic</td>
<td>Semaglutide</td>
<td>Novo Nordisk</td>
<td>NOT FDA-approved for weight loss</td>
</tr>
<tr>
<td>Mounjaro</td>
<td>Tirzepatide</td>
<td>Eli Lilly</td>
<td>NOT FDA-approved for weight loss</td>
</tr>
<tr>
<td>Wegovy</td>
<td>Semaglutide</td>
<td>Novo Nordisk</td>
<td>FDA-approved for weight loss</td>
</tr>
<tr>
<td>Saxenda</td>
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</tbody>
</table>
What challenges is the healthcare system facing with this class of drug?
Increase in GLP-1 injectables used for weight loss

- Increased Demand
- Product Shortages
- Unsatisfactory, Unsafe Alternatives
- Barriers to Access
Which factors must be taken into consideration when exploring compounding options for GLP-1 RAs?
Compounding GLP-1 RA Considerations

- FDA Short List
- Salt forms
- Counterfeit meds
- Sterile vs Non-Sterile conditions

https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
Which barriers exist for patients’ access to these medications?
PRIOR AUTHORIZATIONS
What is Prior Authorization?

• A utilization management process used by payers, or health plans, to assist in determination of coverage
How do payers determine need?

- Payers, also known as health plans or insurance companies, create policies to determine what they will cover
  - Up-to-date Clinical Guidelines
  - Treatment algorithms
  - Clinical studies
  - New Research
  - Cost-effectiveness analysis
  - Health Economics & Outcomes Research
Why is Prior Authorization an issue?

- Restricts Care
- Administrative burden
- Time consuming
What PA criteria is required or can be used for patients to access these medications?
SAMPLE COVERAGE REQUEST LETTER

The example below is for reference only. When drafting a coverage request letter, it should be written on your health care provider’s letterhead. This form should NOT be used as the coverage request letter.

To Whom It May Concern:

I am writing this letter on behalf of my patient, Patient’s Name, to express a concern. My patient is in need of prescription weight loss medication that is currently not covered by your insurance plan.

It is well recognized that obesity is a chronic illness associated with many related diseases, such as dyslipidemia and hypertension. Obesity deserves the same treatment and attention as any other chronic illness. Please contact your health plan or pharmacy benefit manager to pursue coverage for either this individual employee or for the company at large.

Sincerely,
Health Care Provider’s Signature
Health Care Provider’s Name
Are there any other ways to get these medications?
Direct-to-Consumer Healthcare Programs

- **Goal**: improve patient access to medications in the U.S.
- **How does it work?**
  - Patient "visits" an independent telehealth provider
  - HCP provides a prescription electronically
  - Medication is dispensed through 3rd-party pharmacy
  - Medication is delivered directly to patient’s home
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Questions?

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priorauthtraining.org