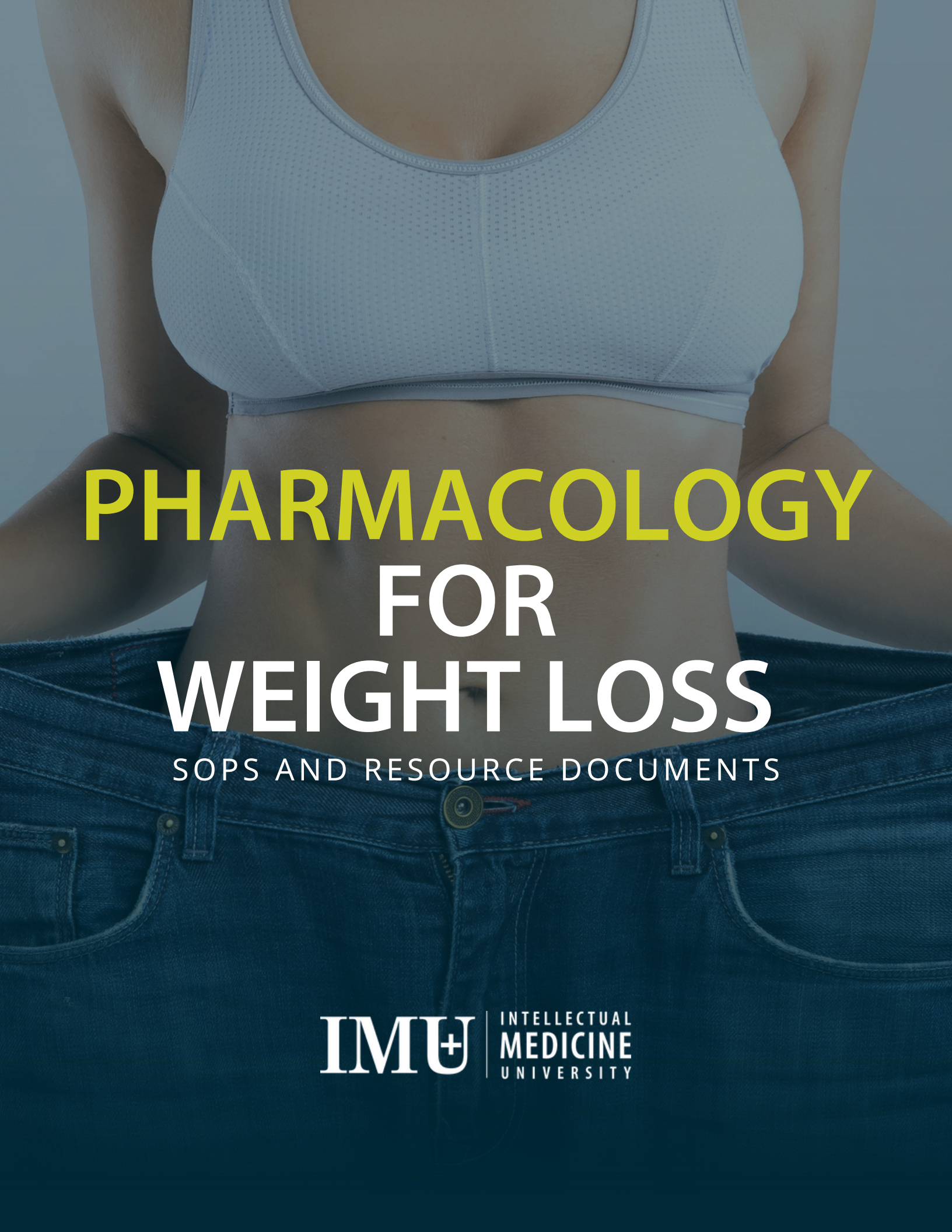

PHARMACOLOGY FOR WEIGHT LOSS

SOPS AND RESOURCE DOCUMENTS

IMU | INTELLECTUAL MEDICINE UNIVERSITY

COMPANY INFORMATION

COMPANY NAME	
ADDRESS	
PHONE	
MEDICAL DIRECTOR/DR/NP NAME AND CREDITIALS	

SOPs

ADMINISTERING BUPROPION IN CLINICAL PRACTICE

	Name/Title	Signature
SOP#		
Effective Date		
Reviewer		
Authorized By		

OBJECTIVE

To provide standardized guidelines for the safe and effective use of bupropion in clinical settings, particularly for weight management, depression, and smoking cessation. This SOP is designed to assist healthcare providers in optimizing bupropion's therapeutic benefits while minimizing potential risks.

SCOPE

This SOP applies to healthcare providers prescribing, administering, and monitoring bupropion therapy for patients in various indications, including weight management, depression, smoking cessation, and other approved uses.

1. Background

Bupropion is an atypical antidepressant that acts as a norepinephrine-dopamine reuptake inhibitor (NDRI). It has proven efficacy in treating major depressive disorder (MDD) and seasonal affective disorder (SAD), as well as aiding in smoking cessation. Bupropion can also be used off-label in weight management, particularly in combination with other medications, due to its appetite-suppressant properties.

2. Indications and Contraindications

Indications:

- **FDA-Approved**: Major depressive disorder (MDD), seasonal affective disorder (SAD), smoking cessation.
- **Off-Label**: Weight management, attention-deficit hyperactivity disorder (ADHD), and bipolar disorder (adjunct therapy).

Contraindications:

- History of seizure disorders (as bupropion lowers the seizure threshold).
- Current or recent use of monoamine oxidase inhibitors (MAOIs).
- Bulimia or anorexia nervosa (increased risk of seizures).
- Known hypersensitivity to bupropion or any component of the formulation.
- Abrupt discontinuation of alcohol or sedatives (increased seizure risk).

3. Dosing and Administration

For Major Depressive Disorder (MDD):

- **Starting Dose**: 150 mg once daily in the morning.
- **Titration**: After 3 days, may increase to 150 mg twice daily (up to 300 mg/day).
- **Maximum Dose**: 450 mg/day in divided doses.

For Smoking Cessation:

- **Starting Dose**: 150 mg once daily for the first 3 days.
- **Titration**: Increase to 150 mg twice daily.
- **Duration**: Typically continue for 7-12 weeks, though some patients may require longer.

For Weight Management (Off-Label):

- **Starting Dose**: 150 mg once daily in combination with lifestyle modification and/or other weight management medications.
- **Titration**: After one week, may increase to 150 mg twice daily as tolerated.

Administration Guidelines:

- Administer with or without food, preferably in the morning to reduce the risk of insomnia.
- Avoid administering bupropion too close to bedtime, as it may cause insomnia.
- Do not crush or chew extended-release (XL or SR) tablets.

Discontinuation:

- **Tapering**: If discontinuing, reduce the dose gradually over 1-2 weeks to avoid withdrawal symptoms.

4. Monitoring and Follow-Up

Baseline Assessment:

- **Medical History**: Assess history of seizure disorder, eating disorders, and alcohol/substance use.
- **Laboratory Tests:** None typically required, but consider baseline liver function tests (LFTs) in patients with hepatic impairment.

Ongoing Monitoring:

- **Initial 3 Months:** Monitor for mood changes, suicidal ideation (especially in young adults), and any emerging side effects.
- **Every 3-6 Months:** Assess for adherence, effectiveness, and any adverse reactions.
- **Weight Management:** Track weight, appetite, and physical activity levels if used off-label for weight management.

Additional Monitoring for Seizures:

- Educate patients on seizure risk, and ensure they report any signs or symptoms of potential seizure activity.

5. Side Effects and Adverse Reaction Management

Common Side Effects:

- Insomnia, headache, dry mouth, dizziness, and weight loss.
- May cause increased anxiety or agitation, especially at the onset of therapy.

Management of Side Effects:

- **Insomnia**: Avoid dosing too late in the day and consider reducing the evening dose if necessary.
- **Dry Mouth**: Encourage increased water intake and sugar-free lozenges if needed.
- **Anxiety or Agitation**: Consider starting at a lower dose and titrating up slowly.

Severe Adverse Reactions:

- **Seizures**: Discontinue immediately if a seizure occurs, as bupropion increases seizure risk, especially at higher doses.
- **Mood Changes and Suicidal Ideation**: Monitor all patients for mood changes and suicidal thoughts, especially at the beginning of therapy.

6. Patient Education and Counseling

Counseling Points:

- Inform patients about the potential side effects, particularly the risk of insomnia and seizure.
- Advise patients to avoid alcohol as it increases the risk of seizures.
- Educate patients about the gradual onset of antidepressant effects, which may take up to 4-6 weeks to notice.
- Encourage patients using bupropion for smoking cessation to set a quit date within the first two weeks of starting therapy.

Missed Dose Instructions:

- If a dose is missed, skip it and take the next dose as scheduled. Do not double up on doses to prevent seizure risk.

7. Documentation Requirements

Initial Visit:

- Record baseline medical history, indication for bupropion, target outcomes, and patient education on potential side effects.

Ongoing Treatment:

- Document all follow-up visits, noting any side effects, dosage adjustments, and patient-reported outcomes.

8. Compliance and Regulatory Guidelines

Controlled Substance Regulations:

- Bupropion is not a controlled substance, but all prescriptions must comply with FDA-approved indications and relevant state regulations for off-label use.

Patient Agreement:

- Ensure the patient understands the risks and benefits of bupropion, including potential side effects and the need for dose consistency.

Provider Training:

- Providers prescribing bupropion should be trained in its pharmacology, therapeutic effects, and adverse effect management.

9. Conclusion

This SOP provides essential guidelines for the safe and effective use of bupropion for its approved and off-label indications. By following this protocol, healthcare providers can ensure that patients benefit from bupropion therapy with minimal risk.

Audited/Revised By	Signature	Date	Notes

STANDARD OPERATING PROCEDURE (SOP) FOR PRESCRIBING LOW DOSE NALTREXONE (LDN) IN WEIGHT MANAGEMENT AND CHRONIC CONDITIONS

	Name/Title	Signature
SOP#		
Effective Date		
Reviewer		
Authorized By		

OBJECTIVE

This SOP provides guidelines for healthcare providers in prescribing Low Dose Naltrexone (LDN) as an adjunct therapy for weight management and chronic conditions. LDN, at low doses, has shown potential in modulating immune response, reducing inflammation, and supporting weight loss in certain patients.

SCOPE

This SOP applies to healthcare providers at [Your Practice/Facility Name] who are authorized to prescribe and monitor LDN for patients seeking weight management or relief from chronic conditions.

1. Background

Low Dose Naltrexone is a formulation of the opioid antagonist naltrexone used at a lower dosage (0.5-4.5 mg) to modulate immune function, reduce inflammation, and support metabolic health. Originally used for opioid addiction in higher doses, LDN has been repurposed off-label to support conditions like chronic pain, autoimmune disease, and weight management.

2. Indications and Contraindications

Indications:

- **Weight Management:** Adjunct therapy for patients struggling with weight loss despite lifestyle modifications.

- **Chronic Conditions:** Management of chronic pain, autoimmune diseases, inflammatory conditions, fibromyalgia, and other conditions where inflammation is a contributing factor.
- **Support for Metabolic Health:** Reduction of metabolic inflammation, appetite control, and improvement of insulin sensitivity.

CONTRAINDICATIONS:

- Known hypersensitivity to naltrexone.
- Current opioid use or opioid dependency, as LDN blocks opioid receptors.
- Severe liver disease.
- Pregnancy or breastfeeding, unless benefits outweigh risks and are prescribed under close supervision.

3. Dosing and Administration

Initial Dose:

- Start at 0.5 mg to 1 mg daily, typically taken at bedtime, as LDN may cause initial sleep disturbances.

Titration:

- Gradually increase by 0.5 mg every 1-2 weeks as tolerated, with a typical target dose of 3-4.5 mg daily.
- Adjust based on patient response and tolerability, with maximum doses typically not exceeding 4.5 mg.

Administration:

- Frequency: Take once daily, ideally at bedtime to align with the body's natural endorphin cycles.

4. Monitoring and Follow-Up

Baseline Assessment:

- **Vital Signs:** Record baseline weight, BMI, blood pressure, and fasting glucose or HbA1c levels.
- **Laboratory Tests:** Liver function tests (LFTs) due to naltrexone metabolism in the liver.

ONGOING MONITORING:

- **First 3 Months:** Monthly check-ins for weight, BMI, side effects, and overall tolerance. Adjust dosing if necessary.
- **Every 6-12 Months:** Re-assessment of liver function, glucose control, and other relevant labs based on patient's underlying health conditions.

Side Effect Monitoring:

- Track any signs of sleep disturbances, vivid dreams, or mild headaches, which are common in early stages and typically resolve.

5. Side Effects and Adverse Reaction Management

Common Side Effects:

- **Sleep Disturbances**: Patients may experience vivid dreams or insomnia, which usually subside after the first few weeks.
- **Headaches**: These can often be managed with hydration and over-the-counter pain relief if needed.
- **Gastrointestinal Disturbance**: Occasionally nausea, which usually improves over time.

Management of Side Effects:

- **Insomnia or Vivid Dreams**: Advise the patient to take LDN earlier in the evening or reduce the dose temporarily.
- **Headaches**: Ensure adequate hydration and suggest taking medication with food.
- **Nausea**: Reduce dose temporarily, then gradually increase as tolerated.

Severe Adverse Reactions:

- If severe adverse reactions such as liver enzyme elevation occur, discontinue use immediately and re-evaluate the patient.

6. Patient Education and Counseling

Counseling Points:

- Explain that LDN is used off-label and the importance of consistent use for optimal results.
- Advise patients to avoid opioids while taking LDN as it blocks opioid receptors, which may impact pain management plans.
- Inform patients that the medication may take several weeks to achieve noticeable effects, especially for immune modulation and weight loss.
- Encourage reporting of any unusual side effects, mood changes, or worsening symptoms.

Missed Dose Instructions:

- If a dose is missed, take it as soon as remembered unless it's close to the next dose. Do not double up to make up for missed doses.

7. Documentation Requirements

Initial Visit:

- Record baseline weight, lab results, patient consent, and goals for LDN therapy. Note that LDN is prescribed off-label and obtain informed consent.

Ongoing Treatment:

- Document all follow-up visits, including dose adjustments, weight changes, any reported side effects, and additional patient counseling as required.

8. Compliance and Regulatory Guidelines

Off-Label Use Documentation:

- Clearly document patient understanding and consent for off-label use of LDN for weight management or chronic conditions.

Provider Training:

- Providers prescribing LDN should have knowledge of the pharmacology, potential benefits, and limitations of low-dose naltrexone use, particularly in off-label contexts.

9. Conclusion

This SOP provides a framework for safely and effectively prescribing Low Dose Naltrexone (LDN) in weight management and chronic condition support. Through proper dosing, monitoring, and patient education, healthcare providers can enhance patient outcomes while minimizing risks associated with LDN therapy.

Audited/Revised By	Signature	Date	Notes

STANDARD OPERATING PROCEDURE (SOP) FOR ADMINISTERING METFORMIN FOR WEIGHT LOSS

	Name/Title	Signature
SOP#		
Effective Date		
Reviewer		
Authorized By		

OBJECTIVE

To outline standardized guidelines for the safe and effective use of metformin in clinical practice, specifically for weight loss management in patients with or without diabetes. This SOP aims to help healthcare providers optimize metformin's potential benefits in weight reduction while monitoring and minimizing risks.

SCOPE

This SOP is intended for healthcare providers prescribing, administering, and monitoring metformin therapy for weight loss in overweight or obese patients, including those with insulin resistance, metabolic syndrome, or polycystic ovary syndrome (PCOS).

1. Background

Metformin is an oral medication traditionally used to treat type 2 diabetes mellitus. It works by reducing hepatic glucose production, increasing insulin sensitivity, and enhancing glucose uptake in peripheral tissues. Due to its effects on insulin sensitivity and potential benefits in reducing appetite, metformin has been used off-label for weight loss, particularly in patients with metabolic abnormalities.

2. Indications and Contraindications

Indications:

- **Off-Label for Weight Loss**: Overweight or obese patients, particularly those with insulin resistance, prediabetes, PCOS, or metabolic syndrome.
- **Adjunctive Therapy**: When used in combination with lifestyle interventions, such as diet and exercise, for improved weight management.

Contraindications:

- Severe renal impairment (eGFR < 30 mL/min/1.73 m²).
- Metabolic acidosis, including diabetic ketoacidosis.
- Known hypersensitivity to metformin or any of its components.
- Conditions predisposing to hypoxia or lactic acidosis (e.g., severe heart failure, severe liver disease).

3. Dosing and Administration

Initial Dose:

- **Standard Release**: Start with 500 mg once daily, preferably with the largest meal to reduce gastrointestinal (GI) side effects.
- **Extended Release (XR)**: Start with 500 mg once daily with the evening meal.

Titration:

- After one week, increase to 500 mg twice daily (standard release) or 1,000 mg once daily (extended release), based on patient tolerance.
- **Maximum Dose**: 2,000 mg per day, either as 1,000 mg twice daily (standard release) or 2,000 mg once daily (extended release).

Administration Guidelines:

- Administer with meals to minimize GI side effects.
- Ensure adequate hydration to reduce the risk of lactic acidosis.

Discontinuation:

- Gradual tapering is not typically required unless for tolerance or adverse effects. Stop metformin if the patient experiences symptoms of lactic acidosis or if renal function significantly declines.

4. Monitoring and Follow-Up

Baseline Assessment:

- **Laboratory Tests**: Baseline eGFR, liver function tests (LFTs), fasting glucose, HbA1c (if diabetic), and vitamin B12 (as metformin can reduce B12 absorption).

Ongoing Monitoring:

- **First 3 Months**: Monitor for weight changes, GI tolerance, and any side effects. Adjust dose based on tolerance and efficacy.
- **Every 6-12 Months**: Re-evaluate renal function (eGFR), liver function, vitamin B12, and monitor weight management goals.

Side Effect Monitoring:

- Track any signs of lactic acidosis (e.g., fatigue, muscle pain, respiratory distress) and symptoms related to B12 deficiency (e.g., fatigue, neuropathy).

5. Side Effects and Adverse Reaction Management

Common Side Effects:

- GI symptoms such as nausea, diarrhea, and abdominal discomfort are common, especially in the initial phase of treatment.

Management of Side Effects:

- **GI Side Effects**: Encourage gradual dose escalation and ensure metformin is taken with food. If GI symptoms persist, consider switching to extended-release formulation.
- **Vitamin B12 Deficiency**: Monitor B12 levels annually, and supplement as needed if deficiency is detected.

Severe Adverse Reactions:

- **Lactic Acidosis**: Although rare, patients should be informed of symptoms and seek immediate medical attention if they experience muscle pain, fatigue, respiratory distress, or abdominal discomfort.

6. Patient Education and Counseling

Counseling Points:

- Explain that metformin is used off-label for weight loss and is most effective when combined with a balanced diet and regular exercise.
- Advise patients to take metformin with food to reduce stomach upset and to report any persistent GI issues.
- Counsel on symptoms of lactic acidosis, particularly if the patient has renal impairment or is dehydrated.
- Educate on the potential for vitamin B12 deficiency, especially with long-term use.

Missed Dose Instructions:

- If a dose is missed, take it as soon as remembered unless it is close to the time for the next dose. Do not double up on doses to prevent GI upset.

7. Documentation Requirements

Initial Visit:

- Record baseline medical history, reason for prescribing metformin, target weight loss goals, and patient education regarding potential side effects and safety precautions.

Ongoing Treatment:

- Document follow-up visits, including any dose adjustments, weight changes, adverse reactions, and lab results as applicable.

8. Compliance and Regulatory Guidelines

Off-Label Use Documentation:

- Ensure the patient is informed that metformin is being used off-label for weight loss, and document informed consent in the patient's record.

Controlled Substance Regulations:

- Metformin is not a controlled substance, but all prescriptions must comply with state and federal regulations, especially when used off-label.

Provider Training:

- Providers prescribing metformin for weight loss should have a solid understanding of its pharmacology, side effect profile, and best practices in weight management.

9. Conclusion

This SOP provides essential guidelines for the effective use of metformin in weight loss management. By following these guidelines, healthcare providers can help patients achieve weight loss goals while minimizing the risk of adverse effects.

Audited/Revised By	Signature	Date	Notes

STANDARD OPERATING PROCEDURE (SOP) FOR ADMINISTERING PHENTERMINE IN CLINICAL PRACTICE

	Name/Title	Signature
SOP#		
Effective Date		
Reviewer		
Authorized By		

OBJECTIVE

To provide standardized guidelines for the safe and effective use of phentermine in treating patients in clinical practice, with a focus on weight management and diabetes care.

SCOPE

This SOP applies to all healthcare providers involved in prescribing, administering, and managing phentermine therapy for patients in clinical practice.

1. Background

Phentermine is an FDA-approved sympathomimetic amine primarily used as a short-term adjunct in a regimen of weight reduction based on caloric restriction, exercise, and behavioral modification in patients with an initial body mass index (BMI) of 30 kg/m^2 or greater, or 27 kg/m^2 with other risk factors. It acts as an appetite suppressant by stimulating the central nervous system.

2. Indications and Contraindications

Indications:

- Patients with BMI ≥ 30 kg/m^2 (obese) or BMI ≥ 27 kg/m^2 with comorbid conditions (e.g., hypertension, diabetes, hyperlipidemia)
- Patients with no history of drug or alcohol misuse

Contraindications:

- Known hypersensitivity to phentermine or sympathomimetic amines
- Cardiovascular disease (e.g., coronary artery disease, arrhythmias, stroke)

- Uncontrolled hypertension
- Hyperthyroidism
- Glaucoma
- Agitated states or history of psychiatric disorders
- History of drug abuse or alcoholism
- Pregnancy or breastfeeding

3. Dosing and Administration
Initial Dose:

- **Standard Dose:** 15 mg, 30 mg, or 37.5 mg once daily in the morning, depending on the patient's response and tolerance. It is generally started at the lowest dose and titrated based on clinical response.
- **Timing:** Administer in the morning before breakfast to avoid insomnia.

Adjustments and Duration:

- Adjust dosage based on the patient's response and tolerability, up to a maximum of 37.5 mg daily.
- Phentermine is typically prescribed for short-term use, up to 12 weeks.
- Evaluate patient adherence and effectiveness every 4 weeks, considering discontinuation if the desired weight loss is not achieved.

Discontinuation Protocol:

- Gradually taper off if patients are taking higher doses for a prolonged period to avoid withdrawal symptoms.

4. Monitoring and Follow-Up
Baseline Assessment:

- Obtain baseline vitals, including blood pressure and heart rate.
- Comprehensive metabolic panel (CMP) and lipid profile
- Assess BMI, medical history, and psychiatric history.
- Evaluate readiness for lifestyle changes and ability to adhere to dietary recommendations.

Ongoing Monitoring:

- **Monthly Check-Ins:** Monitor weight, blood pressure, heart rate, and adherence to the treatment plan.
- **Adverse Effect Monitoring:** Check for symptoms of cardiovascular issues (e.g., palpitations), psychological changes (e.g., mood swings, anxiety), and signs of dependency.
- Document any reported side effects, such as dry mouth, insomnia, constipation, and agitation.

5. Side Effects and Adverse Reaction Management
Common Side Effects:

- Dry mouth, constipation, insomnia, dizziness, restlessness, or elevated blood pressure.
- Provide counseling on managing mild side effects, such as adjusting fluid intake for dry mouth and taking the medication earlier in the day to prevent insomnia.

Severe Reactions and Emergency Protocols:

- **Cardiovascular Symptoms:** If patients experience chest pain, palpitations, or signs of heart failure, discontinue immediately and evaluate.
- **Psychiatric Symptoms:** Discontinue if the patient exhibits severe mood changes, including anxiety, depression, or agitation.
- **Addiction Potential:** Monitor for signs of dependence or misuse, particularly in patients with a history of substance abuse.

Patient Education:

- Educate patients on recognizing and managing common side effects.
- Emphasize the importance of adhering to the prescribed dosage and not taking more than prescribed.

6. Patient Education and Counseling
Lifestyle Counseling:

- Discuss dietary and exercise modifications that align with weight loss goals.
- Encourage patients to set realistic expectations for weight loss and stress the importance of a sustainable lifestyle beyond medication.

Counseling on Phentermine Use:

- Advise patients that phentermine is an adjunct to lifestyle changes, not a standalone solution.
- Explain the potential for tolerance and discuss the importance of using phentermine strictly under medical supervision.

Follow-Up and Adherence:

- Ensure patients are aware of the need for follow-up visits to monitor progress and adjust treatment as needed.
- Encourage patients to report any side effects or difficulties with the regimen.

7. Documentation Requirements
Initial Visit:

- Document the patient's medical history, BMI, and risk factors supporting phentermine prescription.
- Record baseline vitals and lab results.

Ongoing Treatment:

- Document all dosage adjustments, side effects, counseling sessions, and lifestyle modifications.
- Maintain detailed notes on patient progress, weight loss, and any recommendations provided.

Incident Reporting:

- Log any adverse events or complications in the patient's file and report following clinic protocols.

8. Compliance and Regulatory Guidelines

Controlled Substance Regulations:

- Ensure compliance with federal and state regulations for prescribing and dispensing phentermine, a Schedule IV controlled substance.
- Keep track of all phentermine prescriptions and monitor for potential misuse.

Patient Agreement:

- Require patients to sign an informed consent outlining the potential risks, benefits, and responsibilities associated with phentermine use.

9. Conclusion

Following these guidelines ensures that phentermine is used safely and effectively within the practice, contributing to patient weight loss goals while minimizing risks. Proper documentation, patient education, and monitoring are essential components for successful outcomes.

Audited/Revised By	Signature	Date	Notes

STANDARD OPERATING PROCEDURE (SOP) FOR ADMINISTERING SEMAGLUTIDE IN CLINICAL PRACTICE

	Name/Title	Signature
SOP#		
Effective Date		
Reviewer		
Authorized By		

OBJECTIVE

To provide standardized guidelines for the safe and effective use of semaglutide in treating patients in clinical practice, with a focus on weight management and diabetes care.

SCOPE

This SOP applies to all healthcare providers involved in the administration, prescribing, and management of semaglutide within the clinical practice.

1. Background

Semaglutide is a GLP-1 receptor agonist used for glycemic control in diabetes management and as a weight management tool. It has shown efficacy in lowering blood sugar, promoting weight loss, and reducing cardiovascular risks in certain populations. Given its specific effects and potential side effects, careful management is critical.

2. Indications and Contraindications

Indications:

- Type 2 diabetes for glycemic control
- Weight management in patients with a BMI ≥ 30 or ≥ 27 with comorbidities

Contraindications:

- Personal or family history of medullary thyroid carcinoma (MTC)
- Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
- Known hypersensitivity to semaglutide or any of its ingredients
- Pregnancy or planned pregnancy
- Breastfeeding

3. Dosing and Administration
Initiation and Titration:

- **Starting Dose:** 0.25 mg subcutaneously once weekly for 4 weeks
- **Titration:** Increase to 0.5 mg weekly after 4 weeks. If additional weight loss or glycemic control is needed and the patient is tolerating the medication well, consider increasing to 1.0 mg weekly after an additional 4 weeks.
- **Maximum Dose:** 2.4 mg weekly for weight management or as guided by the latest clinical guidelines.

Administration Details:

- Administer semaglutide once weekly on the same day each week.
- Injection sites include the abdomen, thigh, or upper arm.
- Rotate injection sites weekly.
- Do not mix semaglutide with other medications in the same injection.

Missed Dose Protocol:

- If a patient misses a dose, advise them to take the dose as soon as possible within 5 days after the missed dose.
- If more than 5 days have passed, skip the missed dose and resume the regular dosing schedule.

4. Monitoring and Follow-Up
Initial Evaluation:

- Baseline HbA1c, fasting blood glucose, and weight
- Comprehensive metabolic panel (CMP), including kidney and liver function
- Thyroid-stimulating hormone (TSH) for patients with a thyroid history

Ongoing Monitoring:

- Assess weight and glucose control every 4-6 weeks during titration.
- Monitor HbA1c and fasting glucose every 3 months or per individual patient needs.
- Evaluate for side effects such as gastrointestinal discomfort, nausea, and signs of thyroid nodules.

Additional Monitoring:

- For patients with a history of gallbladder disease, monitor for symptoms of gallstones.
- For patients with cardiovascular disease, monitor for signs of tachycardia or other arrhythmias.

5. Side Effects and Adverse Reaction Management
Common Side Effects:

- Nausea, vomiting, and diarrhea—these are often dose-dependent and may decrease over time.
- Counsel patients on dietary modifications (e.g., smaller meals) to minimize gastrointestinal symptoms.

Severe Reactions and Emergency Protocols:

- **Hypoglycemia** (especially if combined with insulin or sulfonylureas): Educate patients on recognizing and managing low blood sugar.
- **Pancreatitis**: Discontinue immediately if symptoms (e.g., severe abdominal pain) occur and evaluate.
- **Thyroid Tumors**: Refer for an ultrasound if there are signs of a thyroid nodule or enlargement.

Patient Education and Documentation:

- Provide thorough education on potential side effects, including symptoms that should prompt immediate medical attention.
- Document all side effects reported, changes in dosing, and patient education efforts in the patient's chart.

6. Patient Education and Counseling
Topics to Cover with Patients:

- Importance of adherence to weekly dosing
- Possible side effects and their management
- Lifestyle changes to maximize effectiveness, such as diet and exercise adjustments
- Avoidance of pregnancy while on semaglutide and the need for effective contraception

Follow-Up Plans:

- Ensure patients understand the importance of regular follow-ups.
- Encourage patients to reach out if they experience intolerable side effects or concerns.

7. Documentation Requirements
Initial Visit:

- Record baseline labs, patient history, and rationale for semaglutide initiation.

Ongoing Treatment:
Document dosage changes, patient-reported outcomes, side effects, and lab results.
Keep detailed notes on patient education, adherence discussions, and lifestyle recommendations.

Incident Reporting:
Log any adverse reactions or complications, following clinic protocols for incident reporting.

8. Conclusion
Following these guidelines ensures that semaglutide is used safely and effectively within the clinical practice. Continuous monitoring, thorough patient education, and careful documentation are essential for optimal outcomes.

Audited/Revised By	Signature	Date	Notes

STANDARD OPERATING PROCEDURE (SOP) FOR ADMINISTERING TIRZEPATIDE IN CLINICAL PRACTICE

	Name/Title	Signature
SOP#		
Effective Date		
Reviewer		
Authorized By		

OBJECTIVE

To establish standardized guidelines for the safe and effective use of tirzepatide, a GLP-1 and GIP receptor agonist, in clinical practice. This SOP is intended to optimize weight management and glycemic control in patients while minimizing adverse effects.

SCOPE

This SOP applies to all healthcare providers involved in prescribing, administering, and managing tirzepatide therapy for patients.

1. Background

Tirzepatide is a novel injectable medication that combines GLP-1 (glucagon-like peptide-1) and GIP (glucose-dependent insulinotropic polypeptide) receptor agonists, commonly used for type 2 diabetes and weight management in obese patients. It works by enhancing insulin secretion, reducing glucagon release, and delaying gastric emptying, which contributes to its weight loss effects.

2. Indications and Contraindications

Indications:

- Adults with type 2 diabetes who require additional glycemic control alongside diet and exercise.
- Obese patients (BMI ≥ 30 kg/m²) or overweight patients (BMI ≥ 27 kg/m²) with at least one weight-related comorbidity, as part of a comprehensive weight management program.

Contraindications:
History of serious hypersensitivity to tirzepatide or any of its components.

- Personal or family history of medullary thyroid carcinoma (MTC) or patients with multiple endocrine neoplasia syndrome type 2 (MEN 2).
- Pregnant or breastfeeding women.
- Severe gastrointestinal disease, such as gastroparesis.

3. Dosing and Administration
Initial Dose:

- **Starting Dose:** 2.5 mg injected subcutaneously once weekly.
- **Escalation Schedule:** Increase dose to 5 mg once weekly after 4 weeks based on tolerance and clinical goals.

Dose Adjustments:

- Gradually increase by 2.5 mg increments every 4 weeks if additional glycemic control or weight loss is required, up to a maximum dose of 15 mg weekly.
- Monitor tolerance, and hold or reduce the dose if adverse gastrointestinal side effects occur.

Administration Guidelines:

- Administer tirzepatide as a subcutaneous injection in the abdomen, thigh, or upper arm.
- Rotate injection sites to avoid lipodystrophy.
- Ensure injections are given on the same day each week. If a dose is missed, administer within 4 days; otherwise, skip and resume the normal schedule.

4. Monitoring and Follow-Up
Baseline Assessment:

- Obtain baseline weight, BMI, and waist circumference.
- Assess baseline fasting blood glucose and HbA1c for diabetic patients.
- Conduct a complete metabolic panel (CMP), lipid profile, and thyroid panel.
- Evaluate for any contraindications or potential high-risk factors.

Ongoing Monitoring:

- **Monthly Check-Ins (First 3 Months):** Monitor for weight loss, blood glucose levels, gastrointestinal tolerance, and injection site reactions.
- **Every 3 Months:** Evaluate HbA1c, weight, blood pressure, and any symptoms suggestive of thyroid abnormalities or other adverse effects.

Duration of Therapy:

- Tirzepatide may be continued as part of a long-term management strategy, depending on clinical effectiveness and tolerance.
- Reassess every 6 months to determine the need for continued therapy.

5. Side Effects and Adverse Reaction Management

Common Side Effects:

- Gastrointestinal (GI): Nausea, vomiting, diarrhea, constipation, abdominal pain.
- Hypoglycemia: Especially in combination with insulin or insulin secretagogues (e.g., sulfonylureas).
- Injection site reactions: Redness, swelling, or itching at the injection site.

Management of Side Effects:

- **GI Side Effects:** Encourage patients to eat smaller, more frequent meals, and to avoid large, high-fat meals. Consider temporarily reducing the dose until symptoms improve.
- **Hypoglycemia:** Educate patients on recognizing hypoglycemia symptoms and managing episodes, especially if on concurrent hypoglycemic agents. Adjust other diabetes medications as needed.
- **Injection Site Reactions:** Rotate injection sites and use topical treatments if necessary.

Severe Adverse Reactions:

- **Thyroid Tumors:** Instruct patients to report symptoms such as a lump in the neck, hoarseness, or difficulty swallowing.
- **Pancreatitis:** Discontinue immediately if pancreatitis is suspected, and monitor the patient's condition.

6. Patient Education and Counseling

Lifestyle Counseling:

- Encourage adherence to a balanced, calorie-controlled diet and regular physical activity.
- Provide guidance on maintaining long-term weight loss strategies.

Counseling on Tirzepatide Use:

- Explain the expected effects, such as appetite suppression, improved glycemic control, and potential weight loss.
- Advise patients on the importance of consistent weekly dosing.
- Discuss the gradual increase in dose and the importance of following the escalation schedule to minimize GI side effects.

Hypoglycemia Education:

- Instruct patients on the recognition and treatment of hypoglycemia, especially if taking other antidiabetic medications.

7. Documentation Requirements

Initial Visit:

- Document the patient's medical history, baseline lab results, and reason for tirzepatide therapy

Ongoing Treatment:

- Record dosing adjustments, adverse reactions, patient-reported outcomes, and any clinical monitoring.
- Document all counseling sessions and provide written materials if applicable.

Incident Reporting:

- Document any adverse events in the patient's record and report to pharmacovigilance authorities as required.

8. Compliance and Regulatory Guidelines

Controlled Substance Regulations:

- Although tirzepatide is not a controlled substance, all prescriptions should comply with FDA-approved labeling and state regulations.

Patient Agreement:

- Ensure the patient understands the potential risks, including the possible association with thyroid tumors, and signs an informed consent if appropriate.

Provider Training:

- All providers prescribing tirzepatide must be trained in GLP-1 and GIP therapy and must review the latest evidence and guidelines regularly.

9. Conclusion

This SOP provides comprehensive guidance for the safe and effective use of tirzepatide in clinical practice. By following these guidelines, healthcare providers can help patients achieve weight and glycemic control goals with minimal risk, enhancing the quality of care.

Audited/Revised By	Signature	Date	Notes

STANDARD OPERATING PROCEDURE (SOP) FOR ADMINISTERING TOPIRAMATE IN CLINICAL PRACTICE

	Name/Title	Signature
SOP#		
Effective Date		
Reviewer		
Authorized By		

OBJECTIVE

To provide standardized guidelines for the safe and effective use of topiramate, particularly in weight management and migraine prevention. This SOP is designed to assist healthcare providers in optimizing the therapeutic benefits of topiramate while minimizing potential side effects.

SCOPE

This SOP applies to healthcare providers who prescribe, administer, and monitor topiramate therapy for patients. While topiramate has FDA-approved indications, it is also used off-label for weight management and other conditions.

1. Background

Topiramate is an anticonvulsant medication that has demonstrated efficacy in reducing appetite and promoting weight loss, in addition to its approved indications for migraine prevention and seizure control. It may be used as part of a comprehensive weight management plan or to address migraines.

2. Indications and Contraindications

Indications:

- **FDA-Approved**: Seizure disorders, migraine prevention.
- **Off-Label**: Weight management, binge eating disorder, and other obesity-related conditions in conjunction with lifestyle modifications.

Contraindications:

- Hypersensitivity to topiramate or any of its components.

- Patients with a history of metabolic acidosis or certain eye conditions (e.g., acute myopia with secondary angle closure glaucoma).
- Pregnancy and breastfeeding due to teratogenic risk.
- Severe renal or hepatic impairment (use with caution and adjust dosage if needed).

3. Dosing and Administration
Initial Dosing for Weight Management:
- **Starting Dose**: 25 mg orally once daily, preferably in the evening.
- **Titration**: Increase the dose by 25 mg every 1-2 weeks as tolerated, up to a typical dose of 100-200 mg daily, split into two doses (morning and evening).

Dosing for Migraine Prevention:
- **Starting Dose**: 25 mg orally once daily, increasing gradually to a maintenance dose of 50-100 mg twice daily as tolerated.

Administration Guidelines:
- Administer with or without food, as tolerated.
- Ensure consistent dosing schedules (e.g., same time each day).
- Patients should stay well-hydrated to reduce the risk of kidney stones.

Discontinuation:
- **Tapering**: If discontinuing, reduce the dose gradually over at least 2-4 weeks to prevent rebound symptoms or withdrawal effects.

4. Monitoring and Follow-Up
Baseline Assessment:
- **Medical History**: Evaluate for kidney disease, metabolic acidosis, mental health history, and eye conditions.
- **Laboratory Tests**: Consider baseline serum bicarbonate, creatinine, liver enzymes, and a comprehensive metabolic panel.

Ongoing Monitoring:
- **Monthly Check-Ins (First 3 Months)**: Monitor weight, appetite, mood changes, and side effects.
- **Every 3-6 Months**: Reassess laboratory markers for metabolic acidosis, electrolyte imbalances, and renal function.
- **Ophthalmologic Evaluation:** Monitor for symptoms such as eye pain or vision changes, particularly during the initial months of treatment.

5. Side Effects and Adverse Reaction Management

Common Side Effects:

- Cognitive issues: Difficulty concentrating, memory impairment.
- Paresthesia (tingling in fingers and toes).
- Appetite suppression, weight loss.
- Gastrointestinal symptoms: Nausea, diarrhea.
- Fatigue, drowsiness, and mood changes.

Management of Side Effects:

- **Cognitive and Mood Changes**: Titrate slowly to minimize these effects, and assess for any pre-existing psychiatric conditions.
- **Hydration for Kidney Stones**: Encourage adequate fluid intake, as topiramate may increase the risk of kidney stones.
- **Metabolic Acidosis**: Periodically check bicarbonate levels; if acidosis is detected, consider dose reduction or discontinuation.

Severe Adverse Reactions:

- **Acute Myopia and Glaucoma**: Discontinue immediately if symptoms occur.
- **Severe Metabolic Acidosis**: Discontinue if unmanageable with supportive care.
- **Suicidal Ideation**: Monitor for depression or suicidal thoughts, particularly in patients with a prior psychiatric history.

6. Patient Education and Counseling

Counseling on Topiramate Use:

- Discuss potential cognitive side effects, including “brain fog” or memory issues, and encourage patients to report these effects if bothersome.
- Instruct patients to avoid alcohol as it may worsen drowsiness and cognitive effects.
- Educate patients on the importance of staying hydrated to reduce the risk of kidney stones.
- Explain the gradual titration schedule and the importance of not abruptly stopping the medication without consultation.

Diet and Lifestyle Counseling:

- Advise patients to follow a balanced, calorie-controlled diet and regular physical activity, as topiramate is most effective when combined with lifestyle changes.

Missed Dose Instructions:

- If a dose is missed, take it as soon as possible, unless it is close to the next dose. Do not double doses.

7. Documentation Requirements

Initial Visit:

- Record baseline medical history, lab results, indication for topiramate, and target outcomes.
- Document patient education on potential side effects, dietary recommendations, and importance of hydration.

Ongoing Treatment:

- Document all follow-up visits, noting any side effects, dosage adjustments, and patient-reported outcomes.
- Record lab results, adverse effects, and any patient concerns or questions addressed.

8. Compliance and Regulatory Guidelines

Controlled Substance Regulations:

- Topiramate is not a controlled substance, but all prescriptions must comply with FDA-approved indications and relevant state regulations for off-label use.

Patient Agreement:

- Ensure the patient understands the potential risks and benefits of topiramate, including side effects and signs of adverse reactions, and has signed informed consent if required by state guidelines.

Provider Training:

- Healthcare providers prescribing topiramate should be trained in its pharmacology, therapeutic effects, and adverse effect management.

9. Conclusion

This SOP for topiramate therapy provides essential guidelines for safe and effective use in weight management, migraine prevention, and other off-label indications. By following this protocol, healthcare providers can ensure that patients benefit from topiramate with minimal risk.

Audited/Revised By	Signature	Date	Notes

STANDARD OPERATING PROCEDURE (SOP) FOR ADMINISTERING ZONISAMIDE FOR WEIGHT LOSS

	Name/Title	Signature
SOP#		
Effective Date		
Reviewer		
Authorized By		

OBJECTIVE

This SOP provides guidelines for the safe and effective use of zonisamide as an off-label treatment for weight loss in overweight and obese patients. Zonisamide, originally an antiepileptic medication, has been shown to support weight reduction by affecting appetite and energy expenditure.

SCOPE

This SOP is intended for healthcare providers prescribing and monitoring zonisamide therapy for weight management in patients with obesity or related metabolic conditions.

1. Background

Zonisamide is an anticonvulsant medication that has demonstrated effectiveness in reducing weight when combined with other weight management strategies. The mechanism is thought to involve modulation of appetite and metabolism by influencing certain neurotransmitters.

2. Indications and Contraindications

Indications:

- **Off-Label for Weight Loss**: Adults with obesity (BMI ≥ 30 kg/m²) or overweight (BMI ≥ 27 kg/m²) with metabolic complications who have not achieved satisfactory results with diet and exercise alone.
- **Adjunctive Therapy**: Use in combination with other pharmacological or lifestyle interventions, such as diet, exercise, or other weight-loss medications, as part of a comprehensive weight management plan.

Contraindications:

- Known hypersensitivity to zonisamide or sulfonamides.
- Severe liver or kidney impairment.
- History of kidney stones or metabolic acidosis.
- History of severe mood disorders or suicidal ideation.
- Pregnant or breastfeeding patients, as zonisamide may carry risks for fetal development.

3. Dosing and Administration

Initial Dose:

- Start with 25 mg once daily, preferably taken in the evening to minimize any sedative effects.

Titration:

- Increase dose by 25 mg every one to two weeks based on tolerance and effectiveness, up to a target dose of 100–200 mg daily.
- Administer as a single dose at bedtime, or divide the dose into twice daily, depending on patient tolerance.

Maintenance Dose:

- Typical maintenance dose ranges from 100 to 200 mg daily, adjusted according to individual response and tolerance.

Discontinuation:

- Gradually taper the dose over one to two weeks to reduce the risk of withdrawal symptoms, especially in patients on higher doses.

4. Monitoring and Follow-Up

Baseline Assessment:

- **Vital Signs**: Record baseline weight, BMI, and blood pressure.
- **Laboratory Tests**: Baseline liver function tests, kidney function tests, bicarbonate levels, and screening for metabolic acidosis.
- **Psychiatric Assessment**: Screen for a history of depression, anxiety, or suicidal ideation, as zonisamide may increase the risk of mood changes.

Ongoing Monitoring:

- **First 3 Months**: Monitor weight and BMI monthly, check for any mood changes, and adjust dosing as necessary.
- **Every 6-12 Months**: Re-evaluate liver and kidney function, as well as bicarbonate levels to monitor for metabolic acidosis.

Side Effect Monitoring:

- Track any signs of metabolic acidosis (e.g., fatigue, muscle weakness), cognitive changes, or psychiatric symptoms (e.g., mood swings, anxiety, depression).

5. Side Effects and Adverse Reaction Management

Common Side Effects:

- Sedation, dizziness, cognitive slowing, loss of appetite, and mild gastrointestinal discomfort.
- **Weight Loss**: While desired, rapid or excessive weight loss should be monitored to ensure nutritional adequacy.

Management of Side Effects:

- **Sedation or Dizziness**: Take the medication at bedtime and adjust dose as needed.
- **Mood Changes**: Discontinue use if mood symptoms become severe or if there is any suicidal ideation. Refer for psychiatric evaluation as needed.
- **Metabolic Acidosis**: Check bicarbonate levels regularly; if metabolic acidosis is detected, lower the dose or discontinue zonisamide and monitor.

Severe Adverse Reactions:

- **Kidney Stones**: Encourage hydration to reduce risk. Discontinue zonisamide if kidney stones develop.
- **Metabolic Acidosis**: Stop zonisamide if persistent acidosis occurs and evaluate renal function.

6. Patient Education and Counseling

Counseling Points:

- Explain that zonisamide is being used off-label for weight loss and that it is part of a comprehensive weight management program.
- Advise patients to take the medication with a full glass of water to help reduce the risk of kidney stones.
- Encourage patients to maintain adequate hydration throughout the day.
- Instruct patients to report any unusual mood changes, cognitive changes, or symptoms of metabolic acidosis (e.g., fatigue, breathing difficulties).
- Explain the importance of regular follow-up appointments and lab tests for safe monitoring.

Missed Dose Instructions:

- If a dose is missed, take it as soon as remembered unless it is close to the time for the next dose. Do not double up on doses to avoid adverse effects.

7. Documentation Requirements

Initial Visit:

- Record baseline patient information, target weight management goals, and patient education on potential risks, benefits, and the off-label nature of zonisamide for weight loss.

Ongoing Treatment:

- Document follow-up visits, including dose adjustments, weight change, lab results, and any side effects or adverse reactions noted.

8. Compliance and Regulatory Guidelines

Off-Label Use Documentation:

- Ensure that the patient is informed that zonisamide is being used off-label for weight loss and obtain informed consent, which should be documented in the patient's record.

Controlled Substance Regulations:

- Zonisamide is not a controlled substance, but all prescriptions must comply with state and federal regulations, especially when used off-label.

Provider Training:

- Providers should have adequate knowledge of zonisamide's pharmacology, side effect profile, and best practices for monitoring in a weight management setting.

9. Conclusion

This SOP outlines the effective use of zonisamide as part of a weight management strategy. By adhering to these guidelines, healthcare providers can help patients achieve sustainable weight loss while minimizing potential risks associated with zonisamide therapy.

Audited/Revised By	Signature	Date	Notes

INFORMED CONSENTS

INFORMED CONSENT | PHENTERMINE (ADIPEX) OR PHENDIMETRAZINE (BONTRIL)

I hereby acknowledge that I have been informed about the use of Phentermine/Phendimetrazine in the weight loss program provided by Intellectual Medicine. I understand that these medications are prescription appetite suppressants designed to assist with weight loss when combined with a proper diet and exercise regimen.

Medication Details: I understand that Phentermine/Phendimetrazine are stimulant medications that work by suppressing my appetite, leading to reduced caloric intake and aiding in weight loss. I have been informed about the intended use, dosage, and potential side effects associated with these medications. I understand that phentermine is a "Schedule 4" controlled substance, and that Phendimetrazine is a "Schedule 3" controlled substance. Schedule 3 substances according to the DEA website have a “moderate to low potential for physical and psychological dependence.“ Schedule 4 substances have a “low potential for abuse and low risk of dependence.“

Benefits and Risks: I am aware that Phentermine/Phendimetrazine can help control my appetite, making it easier to adhere to my new eating plan. However, I understand that these medications may also cause side effects such as increased heart rate, elevated blood pressure, insomnia, tremor, delayed or obstructed urinary flow (generally occurs only in men), rare cases of primary pulmonary hypertension and dry mouth. I have been informed about the risks and benefits and have had the opportunity to ask questions.

Commitment and Follow-up: I acknowledge that the success of this weight loss program relies on my commitment to maintaining a healthy lifestyle, including regular exercise and a balanced diet. I agree to attend follow-up appointments as scheduled to monitor my progress, discuss any concerns, and adjust the treatment plan if necessary.

Medical History and Monitoring: I have provided my healthcare provider with a complete and accurate medical history, including any allergies, current medications, and existing health conditions. I understand the importance of regular monitoring and will promptly report any unusual symptoms or side effects to my healthcare provider.

Contraindications - history of heart diseases, untreated hyperthyroidism, glaucoma, bipolar or emotional instability, pregnant or nursing women, history of drug abuse, and those considering combination use with other anorectic agents like phentermine and phendimetrazine together.

I acknowledge understanding the details, risks, and alternatives of using Phentermine/Phendimetrazine in the weight loss program. I provide my informed consent for participation and release _____ from any related liabilities.

Print Name **Signature** **Date**

SEMAGLUTIDE INFORMED CONSENT

Semaglutide is a medication prescribed with diet and exercise to help manage weight in adults with high BMI. It's not suitable for those with a history of pancreatitis and is not a replacement for insulin or meant for patients with type 1 diabetes or diabetic ketoacidosis.

While using Semaglutide, it is highly recommended that you:

1. Focus on fruits and vegetables that are high in fiber.
2. Eat small high protein meals as digestion is slowed down while on this medication.
3. Avoid foods high in fat and fried foods as they take longer to digest.
4. Limit alcohol intake as this medication can lower blood pressure.
5. Drink at least 32 oz of water a day to avoid constipation.

Semaglutide is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2, and in patients with known hypersensitivity to semaglutide or to any of the product components.

- Risk of Thyroid C-Cell Tumors: If thyroid hormone levels are high or nodules are found, patients should see an endocrinologist for further evaluation.
- Pancreatitis: Watch for signs of pancreatitis (persistent severe abdominal pain, possibly with vomiting). If suspected, stop Semaglutide immediately; if confirmed, do not resume.
- Diabetic Retinopathy Complications: In a 2-year trial for high-risk type 2 diabetes patients, Semaglutide showed more diabetic retinopathy complications (3.0%) compared to placebo (1.8%). Patients with a history of diabetic retinopathy had a higher risk. Semaglutide's long-term impact on retinopathy is unknown. Patients with this history should be monitored.
- Hypoglycemia: The risk of hypoglycemia is increased when Semaglutide is used in combination with insulin secretagogues (eg, sulfonylureas) or insulin.
- Acute Kidney Injury: GLP-1 receptor agonists like Semaglutide may lead to kidney problems, even in patients without prior issues. Monitor patients, especially those with gastrointestinal symptoms, for kidney function when starting or increasing Semaglutide doses.
- Hypersensitivity: Stop Semaglutide if severe allergic reactions like anaphylaxis or angioedema happen. Provide standard care and monitor until symptoms resolve. Be cautious if the patient has a history of such reactions with other GLP-1 receptor agonists.

Common side effects of Semaglutide include nausea, vomiting, diarrhea, abdominal pain, redness at injection site, and constipation. It may interact with other medications, potentially affecting their absorption and causing hypoglycemia. Adjustments in dosage might be necessary.
Surgery - I understand that if I have a planned surgery, I should stop using semaglutide 2 weeks prior due to the fact that it slows gastric emptying.

Do not share Semaglutide injections; it can cause serious infections. If I experience side effects, I'll stop and contact my prescriber. I've had my questions answered and consent to Semaglutide use. I've done required tests, informed about allergies, and understand possible side effects. No guarantees about weight loss results. I certify that I am not pregnant or plan to become pregnant.

Patient Name: _____

Patient Signature: _____ Date:_____

CONSENT FOR TREATMENT WITH TIRZEPATIDE FOR WEIGHT LOSS

I, _____, hereby consent to undergo treatment with tirzepatide for the purpose of weight loss under the care of _____ at _____.

Purpose: Tirzepatide is a medication prescribed to aid in weight loss for individuals struggling to achieve significant weight reduction through diet and exercise alone.

Benefits: Tirzepatide has shown promising results in clinical trials, demonstrating significant weight loss and improvements in metabolic health markers such as blood sugar levels and cholesterol levels.

Risks: I understand that tirzepatide, like any medication, carries potential risks and side effects. These may include gastrointestinal symptoms (such as nausea, vomiting, diarrhea), injection site reactions, hypoglycemia (low blood sugar), and rare but serious allergic reactions.

Monitoring: I understand that regular monitoring of my progress will be necessary while taking tirzepatide. This may include frequent follow-up appointments and laboratory tests to assess my response to the medication and manage any potential side effects.
Alternative Options: I acknowledge that alternative weight loss strategies will be discussed with me if tirzepatide is not suitable for me or if I experience intolerable side effects.

I have been given the opportunity to ask questions and have received satisfactory answers regarding the use of tirzepatide for weight loss. I understand the information provided to me and agree to undergo treatment with tirzepatide as outlined above.

I acknowledge having received full and clear information regarding my treatment options for weight loss.

I have attempted other forms of weight loss and have been unable to achieve success with this aspect of my healthcare.

I request voluntary enrollment in _____ treatment. I have been given the opportunity to consider other alternatives and choose this alternative without pressure or coercion as being in my best interest.

I understand that weight loss treatment includes four or six months of active treatment. Treatments include regularly scheduled sessions with my counselor. It is my responsibility to attend all of these meetings as scheduled.

I understand that I will be requested to make permanent changes in my current eating patterns and activity levels.

I understand that meal replacement therapy may be offered to me and that I will be given the option to pursue that recommendation, if I so choose.

In some situations, “off-label” prescription medications may be used to assist in weight loss management. I understand that “off-label” means that the drug is being used for a purpose other than what is common practice in medicine and does not imply inappropriate use. The medications will be used in the doctor’s best judgment regarding what would be most advantageous to achieve my medical goals. It is my responsibility to report any side effects immediately. It is my responsibility to take medications only as prescribed. It is my responsibility to report to _____ any and all other medications I am using including over the counter medications, nutritional supplements, and medications prescribed by other doctors.

I have been complete and honest in my medical and psychiatric history. I understand that _____ is intended to achieve significant long-term weight reduction. I understand that it is not intended as treatment for Bulimia, Anorexia, or any other eating disorders.

I understand that_____ is not responsible for my general health care through _____, but that I will continue receiving ongoing medical care through my usual doctors.

I have not been promised or guaranteed any predetermined outcome regarding the amount of weight to be lost. I understand that in some cases, treatment can result in no weight loss at all.

I understand that weight loss treatment is a lifelong commitment and failure to commit to an ongoing maintenance program will most likely result in a regaining of weight.
I understand that weight loss can expose me to potential risks including but not limited to; gallstone formation, hair thinning, skin laxity, fatigue, poor energy, loss of muscle strength, low blood sugar, low blood pressure, episodes of fainting, constipation, diarrhea, heart palpitations. If I experience these or any other symptoms, I know to call the doctor’s office immediately.

I cannot participate in this program if I am pregnant or lactating (nursing a baby) for less than twelve weeks.

If I become pregnant or suspect that I am pregnant, I will immediately notify _____.

I acknowledge responsibility for my own health. I hereby assume all risks and hazards associated with, or which may arise from treatment in _____ weight loss program.

The undersigned has read and understood all of the above information.

Printed Name_____**DOB**_____

Signature _____**Date**_____

CONSENT FOR TREATMENT WITHLOW DOSE NALTREXONE (LDN) FOR WEIGHT LOSS

I understand that low-dose naltrexone is not FDA approved to treat any medical condition including; chronic pain, neuropathy, or obesity.

I understand that I am using this product “off label” for treatment objectives that I have discussed with my provider.

I understand that low-dose naltrexone is a compound drug not manufactured by pharmaceutical companies, and that it is not covered by my health insurance.

Naltrexone hydrochloride is contraindicated in

1. Patients receiving opioid analgesics.
2. Patients currently dependent on opioids, including those currently maintained on opiate agonists (e.g., methadone) or partial agonists (e.g., buprenorphine)
3. Patients in acute opioid withdrawal.
4. Any individual who has failed the naloxone challenge test or who has a positive urine screen for opioids.
5. Any individual with a history of sensitivity to naltrexone hydrochloride or any other components of this product.It is not known if there is any cross-sensitivity with naloxone or the phenanthrene containing opioids.

WARNINGS:
Precipitated Opioid Withdrawal
The symptoms of spontaneous opioid withdrawal (which are associated with the discontinuation of opioid in a dependent individual) are uncomfortable, but they are not generally believed to be severe or necessitate hospitalization. However, when withdrawal is precipitated abruptly by the administration of an opioid antagonist to an opioid-dependent patient, the resulting withdrawal syndrome can be severe enough to require hospitalization. Symptoms of withdrawal have usually appeared within five minutes of ingestion of naltrexone hydrochloride and have lasted for up to 48 hours. Mental status changes including confusion, somnolence and visual hallucinations have occurred. Significant fluid losses from vomiting and diarrhea have required intravenous fluid administration. Review of postmarketing cases of precipitated opioid withdrawal in association with naltrexone treatment has identified cases with symptoms of withdrawal severe enough to require hospital admission, and in some cases, management in the intensive care unit.

To prevent the occurrence of precipitated withdrawal in patients dependent on opioids, or exacerbation of a pre-existing subclinical withdrawal syndrome, opioid-dependent patients, including those being treated for alcohol dependence, should be opioid-free (including tramadol) before starting naltrexone hydrochloride treatment. An opioid-free interval of a minimum of 7 to 10 days is recommended for patients previously dependent on short-acting opioids. Patients transitioning from buprenorphine or methadone may be vulnerable to precipitation of withdrawal symptoms for as long as two weeks.

If a more rapid transition from agonist to antagonist therapy is deemed necessary and appropriate by the healthcare provider, monitor the patient closely in an appropriate medical setting where precipitated withdrawal can be managed.

In every case, healthcare providers should always be prepared to manage withdrawal symptomatically with non-opioid medications because there is no completely reliable method for determining whether a patient has had an adequate opioid-free period. A naloxone challenge test may be helpful; however, a few case reports have indicated that patients may experience precipitated withdrawal despite having a negative urine toxicology screen or tolerating a naloxone challenge test (usually in the setting of transitioning from buprenorphine treatment). Patients should be made aware of the risks associated with precipitated withdrawal and encouraged to give an accurate account of last opioid use. Patients treated for alcohol dependence with naltrexone hydrochloride should also be assessed for underlying opioid dependence and for any recent use of opioids prior to initiation of treatment with naltrexone hydrochloride. Precipitated opioid withdrawal has been observed in alcohol-dependent patients in circumstances where the prescriber had been unaware of the additional use of opioids or co-dependence on opioids.

Hepatotoxicity
Cases of hepatitis and clinically significant liver dysfunction were observed in association with naltrexone hydrochloride exposure during the clinical development program and in the postmarketing period. Transient, asymptomatic hepatic transaminase elevations were also observed in the clinical trials and postmarketing period. When patients presented with elevated transaminases, there were often other potential causative or contributory etiologies identified, including pre-existing alcoholic liver disease, hepatitis B and/or C infection, and concomitant usage of other potentially hepatotoxic drugs. Although clinically significant liver dysfunction is not typically recognized as a manifestation of opioid withdrawal, opioid withdrawal that is precipitated abruptly may lead to systemic sequelae, including acute liver injury.

Patients should be warned of the risk of hepatic injury and advised to seek medical attention if they experience symptoms of acute hepatitis. Use of naltrexone hydrochloride should be discontinued in the event of symptoms and/or signs of acute hepatitis.

Depression and Suicidality
Depression, suicide, attempted suicide and suicidal ideation have been reported in the postmarketing experience with naltrexone hydrochloride used in the treatment of opioid dependence. No causal relationship has been demonstrated. In the literature, endogenous opioids have been theorized to contribute to a variety of conditions.

Alcohol-and opioid-dependent patients, including those taking naltrexone hydrochloride, should be monitored for the development of depression or suicidal thinking. Families and caregivers of patients being treated with naltrexone hydrochloride should be alerted to the need to monitor patients for the emergence of symptoms of depression or suicidality, and to report such symptoms to the patient's healthcare provider.

Pregnant Women
There are no adequate and well-controlled studies in pregnant women. Naltrexone hydrochloride should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers
In animal studies, naltrexone and 6-β-naltrexol were excreted in the milk of lactating rats dosed orally with naltrexone. Whether or not naltrexone hydrochloride is excreted in human milk is unknown. Because many drugs are excreted in human milk, caution should be exercised when naltrexone hydrochloride is administered to a nursing woman.

Drug Interactions
Studies to evaluate possible interactions between naltrexone hydrochloride and drugs other than opiates have not been performed. Consequently, caution is advised if the concomitant administration of naltrexone hydrochloride and other drugs is required.

Carcinogenesis, Mutagenesis and Impairment of Fertility The following statements are based on the results of experiments in mice and rats. The potential carcinogenic, mutagenic and fertility effects of the metabolite 6-β-naltrexol are unknown.

Adverse reactions
The following adverse reactions were reported for patients using full dose naltrexone for the purpose of treating opioid addiction. It is not known to what extent they may apply to patients using LDN (Low Dose Naltrexone)

The following adverse reactions have been reported both at baseline and during the naltrexone hydrochloride clinical trials in opioid addiction at an incidence rate of more than 10%:

Difficulty sleeping, anxiety, nervousness, abdominal pain/cramps, nausea and/or vomiting, low energy, joint and muscle pain, and headache.

The incidence was less than 10% for:

Loss of appetite, diarrhea, constipation, increased thirst, increased energy, feeling down, irritability, dizziness, skin rash, delayed ejaculation, decreased potency, and chills.

I understand that if I experience any negative side effects that I am to stop the drug immediately and contact my prescriber.

Patient Signature_____

Print Name_____ **Date**_____

BLOOD DRAW | INFORMED CONSENT

I, _____ (DOB: ____/_____/_____), do hereby consent to the drawing of a blood sample for the purpose of performing laboratory testing to help guide treatment recommendations. I have had the opportunity to read and consider (COMPANY NAME) Privacy Practices Notice to my satisfaction prior to consent. Furthermore, I hereby release and forever discharge for myself, my heirs, executors, administrators and assignees, Intellectual Medicine and their employees, owners and representatives, as well as the company sponsoring this event and their agents, representatives, employees, successors, and assignees from any and all claims, demands, actions and causes of action, which may result from the blood draw or any services performed by _____.

I understand that the risks involved with blood draws include, but are not limited to, discomfort at the site of the blood draw, possible bruising, redness and swelling around the site, bleeding at the sight, feeling of lightheadedness when blood is being drawn, and rarely, an infection at the site of the blood draw.

I understand and accept that data derived from this blood draw is considered preliminary only and does not constitute any kind of diagnosis. It is my responsibility for initiating a follow-up examination to confirm results and obtain professional advice and medical treatment that may be required by my primary care provider.

_____ will keep my results confidential and will only release information to other organizations with my consent.

I have read this consent form. All of the questions I have asked have been answered to my satisfaction. I agree with this procedure.

_____

Patient Signature

_____

Print Name

_____

Date

BONUS MATERIAL

BONUS: WEIGHT LOSS PROGRAM CLINIC PROTOCOL

4-week package

- IV infusion on weeks 1 and 4
- IM injections on weeks 1, 2, 3, 4
  - IVs = 2
  - IM = 4

8-week Package

- IV infusion on weeks 1, 2, 4, 6, 8
- IM injections on weeks 1, 2, 3, 4, 5, 6, 7, 8
  - IVs = 5
  - IMs = 8

12-week Package

- IV infusion on weeks 1, 2, 4, 6, 8, 12
- IM injections on weeks 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12
  - IVs = 6
  - IMs – 12

WEIGHT MANAGEMENT IV INFUSION & IM FORMULATIONS

Description	BONUS PROTOCOL MATERIAL – IMED's IV infusion for weight loss and specialized IM injection
IV	Vitamin C – 1000 mgB12 – 1000 mcg B Complex – 1 ml Biotin (B7)– 10 mg Carnitine – 100 mg Dexpanthenol (B5) – 250 mg Glutamine 60 mg Mix in 250 - 500 mL Normal Saline 0.9% (Calculate Osmolarity)
IM	Lipo Shots (without methionine) 2 x week for one month, then weekly ongoing for as long as needed or desired
Optional Boosters	B12 1000 mcg, arginine 400 mg
Protocol	Weekly x 4, then every other week for 2 months, then monthly maintenance.
Expectation Management	IVs and IM shots are for supporting the body in their weight loss program while changing eating habits and behaviors. They can boost metabolism and move fat that has been stored. They are not intended for a stand-alone weight loss program.
Labs	A1C, lipids, High Sensitivity CR, CBC, Thyroid Panel, Vitamin D
Supplements	**see guide for all supplements
IM Injection	B12 (2000 mcg) + GACLIV (Glutamine / Arginine / Carnitine / Leucine / Isoleucine / Valine) 2.5 mL Inject in glute only 1-3x weekly
Notes	This is a great area to offer at-home injections. Clients can purchase 1-3 vials through a 503A compounding pharmacy. *IV and injections support dietary change, but have little impact on obesity on their own. These are complementary treatments!

WEIGHT LOSS SUPPORT: VITAMINS, MINERALS, AND SUPPLEMENTS

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This document outlines the key vitamins, minerals, and supplements that can aid in weight loss and support micronutrient health. Each supplement includes the mechanism of action, recommended dose, and the rationale for its use.

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1. Alpha-Lipoic Acid (ALA)

- **Mechanism of Action**: Improves insulin sensitivity and enhances energy metabolism.
- **Dose**: 300–600 mg daily.
- **Why It's Used**: Reduces oxidative stress and supports healthy glucose levels.

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2. B Complex

- **Mechanism of Action**: B vitamins play essential roles in energy production, metabolism of carbohydrates, fats, and proteins, and reducing fatigue.
- **Dose**: As per label instructions (commonly includes B1, B2, B3, B5, B6, B7, B9, and B12).
- **Why It's Used**: Enhances energy levels, reduces fatigue, and supports overall metabolic health.

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3. Berberine

- **Mechanism of Action**: Activates AMP-activated protein kinase (AMPK), which improves glucose metabolism and insulin sensitivity.
- **Dose**: 500 mg two to three times daily.
- **Why It's Used**: Helps with blood sugar control and weight loss by improving metabolic health.

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4. Caffeine

- **Mechanism of Action**: Stimulates the central nervous system, increases thermogenesis, and enhances fat oxidation.
- **Dose**: 100–200 mg up to three times daily (limit to avoid overstimulation).
- **Why It's Used**: Boosts energy, increases metabolism, and supports fat burning during physical activity.

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5. Chromium Picolinate

- **Mechanism of Action**: Enhances insulin sensitivity and glucose metabolism by improving the action of insulin at the cellular level.
- **Dose**: 200–500 mcg daily.
- **Why It's Used**: Helps control blood sugar and reduce sugar cravings.

6. CLA (Conjugated Linoleic Acid)

- **Mechanism of Action**: Reduces fat storage by influencing enzymes involved in fat metabolism.
- **Dose**: 3–4 grams daily.
- **Why It's Used**: Helps reduce body fat and maintain lean muscle mass.

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7. Coenzyme Q10 (CoQ10)

- **Mechanism of Action**: Supports mitochondrial energy production and acts as a powerful antioxidant.
- **Dose**: 100–200 mg daily.
- **Why It's Used**: Enhances energy levels and metabolic efficiency.

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8. Coffee Bean Extract (Green Coffee Bean)

- **Mechanism of Action**: Contains chlorogenic acid, which reduces carbohydrate absorption and enhances fat metabolism.
- **Dose**: 200–400 mg daily.
- **Why It's Used**: Supports fat loss and improves blood sugar regulation.

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9. Creatine

- **Mechanism of Action**: Replenishes ATP stores during high-intensity exercise, improving strength and lean muscle mass.
- **Dose**: 3–5 grams daily.
- **Why It's Used**: Preserves lean body mass, enhances workout performance, and supports metabolism.

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10. Fiber (Psyllium Husk, Glucomannan)

- **Mechanism of Action**: Promotes satiety by slowing gastric emptying and reducing appetite. It also improves blood sugar control.
- **Dose**: 3–5 grams daily with water.
- **Why It's Used**: Helps control hunger, improve digestion, and regulate blood sugar.

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11. Glutamine

- **Mechanism of Action:** Supports muscle recovery, reduces sugar cravings, and improves gut health.
- **Dose:** 5–10 grams daily.
- **Why It's Used:** Aids in recovery, supports gut function, and reduces cravings during calorie restriction.

12. Green Tea Extract (EGCG)

- **Mechanism of Action**: Increases fat oxidation and thermogenesis by enhancing norepinephrine activity.
- **Dose**: 400–500 mg daily, standardized to 50% EGCG.
- **Why It's Used**: Boosts metabolism and supports fat loss.

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13. Inositol

- **Mechanism of Action**: Improves insulin sensitivity, supports liver health, and balances hormones (e.g., PCOS-related weight issues).
- **Dose**: 2–4 grams daily.
- **Why It's Used**: Helps with blood sugar regulation, reduces insulin resistance, and supports metabolic health.

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14. L-Carnitine

- **Mechanism of Action**: Transports fatty acids into mitochondria for energy production, enhancing fat metabolism.
- **Dose**: 500–2,000 mg daily.
- **Why It's Used**: Supports energy production and fat oxidation, especially during exercise.

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15. L-Arginine

- **Mechanism of Action**: Increases nitric oxide production, which improves blood flow and enhances exercise performance.
- **Dose**: 3–6 grams daily.
- **Why It's Used**: Supports fat burning by enhancing workout efficiency and promotes lean muscle development.

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16. Magnesium

- **Mechanism of Action:** Acts as a cofactor for enzymes involved in energy metabolism, insulin signaling, and muscle function.
- **Dose:** 300–400 mg daily (preferably as magnesium glycinate or citrate for better absorption).
- **Why It's Used:** Helps with blood sugar regulation, reduces insulin resistance, and supports energy production.

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17. Melatonin

- **Mechanism of Action:** Improves sleep quality, which is essential for metabolic regulation and weight loss.
- **Dose:** 1–5 mg nightly.
- **Why It's Used:** Promotes better sleep, reduces stress hormones, and supports fat loss.

18. Omega-3 Fatty Acids (Fish Oil)

- **Mechanism of Action**: Improves fat metabolism by increasing fat oxidation and reducing fat storage. It also has anti-inflammatory effects.
- **Dose**: 1,000–2,000 mg EPA/DHA daily.
- **Why It's Used**: Promotes fat loss, supports cardiovascular health, and reduces inflammation linked to obesity.

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19. Probiotics

- **Mechanism of Action**: Modulates the gut microbiome, which plays a role in energy extraction, fat storage, and inflammation.
- **Dose**: 10–20 billion CFUs daily, containing strains like Lactobacillus gasseri and Bifidobacterium breve.
- **Why It's Used**: Improves gut health, reduces bloating, and supports metabolic health.

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20. Vitamin B12

- **Mechanism of Action**: Supports energy production by aiding in the conversion of food into energy. It also plays a role in red blood cell production.
- **Dose**: 1,000 mcg weekly (IM injection) or 500–1,000 mcg daily (sublingual).
- **Why It's Used**: Improves energy levels and reduces fatigue, which is crucial during weight loss.

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21. Vitamin D

- **Mechanism of Action**: Regulates calcium homeostasis and influences insulin sensitivity by acting on pancreatic beta cells. It also plays a role in reducing inflammation.
- **Dose**: 2,000–5,000 IU daily, depending on serum levels.
- **Why It's Used**: Low vitamin D levels are associated with obesity, insulin resistance, and difficulty losing weight.

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22. Zinc

- **Mechanism of Action**: Regulates appetite and supports thyroid function, which is critical for metabolism.
- **Dose**: 10–15 mg daily.
- **Why It's Used**: Improves thyroid function and reduces inflammation, which supports weight loss.

FINAL THOUGHTS: YOUR JOURNEY TO TRANSFORMATIVE PATIENT CARE

As you reach the end of this supplement, remember that knowledge is just the beginning. What sets great providers apart is not only their expertise but their willingness **to apply what they've learned, innovate, and lead the way in patient care.**

At **Intellectual Medicine University**, we believe in empowering healthcare professionals to think beyond the traditional, challenge outdated norms, and embrace the future of weight loss medicine with confidence and skill.

Dr. Stephen Petteruti has spent over 30 years pioneering advanced, **evidence-based approaches** to anti-aging and metabolic health. His deep understanding of **hormone optimization, functional medicine, and cellular therapy** has helped transform thousands of lives.

As a **Nurse Practitioner and business leader**, I (Shannon Petteruti) have dedicated my career to **bridging the gap between science and practical application**, ensuring that providers like you have the tools to **implement powerful, patient-centered solutions** in your practice.

Now, it's **your time** to take this knowledge and make an impact. Whether you're prescribing, educating, or guiding patients through their weight loss journey, know that **you are part of a movement**—a new era of healthcare professionals shaping the future of **metabolic medicine.**

Stay curious. Stay bold. And most importantly, stay committed to the **patients who trust you to guide them toward better health.** We're honored to be a part of your journey. **Welcome to the future of weight loss medicine.**

Dr. Stephen Petteruti & Shannon Petteruti, NP
Intellectual Medicine University