

Peptide Therapy Clinical Considerations

A concise safety and documentation resource for clinicians and professional partners

Purpose

Use this guide to support screening, informed discussion, documentation, and referral decisions. It is not a prescribing protocol and does not provide dosing instructions. Product selection and treatment decisions remain the responsibility of the licensed treating clinician.

Start with regulatory status

- Confirm whether the proposed product and intended use are FDA approved, off label, compounded, investigational, or not legally available for the intended patient.
- Compounded drugs are not FDA approved; FDA does not review them before marketing for safety, effectiveness, or quality.
- A compounded preparation should be tied to a documented patient-specific clinical need and sourced through an appropriately licensed pharmacy.
- Peptide-related impurities, aggregation, contamination, potency variation, and immunogenicity may create clinically meaningful risk.

Pre-treatment review

Treatment objective	Define the symptom, diagnosis, measurable goal, reasonable time horizon, and stopping criteria.
Medical history	Review cancer history, endocrine disease, diabetes, cardiovascular disease, kidney and liver disease, pregnancy potential, fertility goals, sleep apnea, edema, neuropathy, and prior adverse reactions.
Medication review	Reconcile prescriptions, compounded products, supplements, grey-market products, anticoagulants, glucose-lowering agents, and products affecting the same physiologic pathway.
Baseline data	Record vital signs, weight and body composition when relevant, focused examination, and clinically indicated laboratory results.
Product verification	Document pharmacy, formulation, concentration, storage instructions, lot information when available, and the patient-specific reason for compounding.

Patient discussion

- Explain the quality of evidence, known benefits, material risks, uncertainties, alternatives, cost, monitoring plan, and circumstances requiring treatment to stop.
- State clearly when long-term human safety data are limited or when use is investigational or compounded.

- Review injection technique, storage, missed-dose instructions from the prescriber or pharmacy, sharps disposal, and the prohibition on sharing medication.
- Warn against substituting online or grey-market products and against changing concentration or dose without prescriber confirmation.

Monitoring framework

Early follow-up	Confirm product identity, administration technique, adherence, tolerability, vital signs, and medication interactions.
Effectiveness	Track only outcomes relevant to the documented treatment objective. Avoid continuing indefinitely without meaningful benefit.
Laboratory monitoring	Individualize testing to the product, physiologic pathway, comorbidities, baseline abnormalities, and emerging symptoms.
Adverse events	Document timing, severity, product and lot details when available, intervention, outcome, and whether the event was reported to the pharmacy or FDA MedWatch.
Continuation decision	Reassess benefit, burden, uncertainty, cost, adherence, and alternatives at defined intervals.

Urgent evaluation or treatment hold

- Signs of anaphylaxis or severe allergic reaction
- Chest pain, fainting, new neurologic deficit, or severe shortness of breath
- Persistent vomiting, inability to maintain hydration, severe abdominal pain, or suspected pancreatitis
- New severe edema, rapid weight change, marked glucose abnormality, or progressive numbness or weakness
- Pregnancy, a new cancer diagnosis, serious infection, hospitalization, or an unexpected severe reaction

Documentation essentials

- Diagnosis or treatment indication and the evidence supporting medical necessity.
- Why an FDA-approved option is not appropriate, when a compounded product is chosen.
- Product, concentration, route, instructions, pharmacy, monitoring plan, and follow-up interval.
- Material risks, alternatives, uncertainties, patient questions, informed consent, and return precautions.
- Outcome measures and the decision to continue, modify, hold, or discontinue therapy.

References

FDA. Human Drug Compounding. <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding>

FDA. Certain Bulk Drug Substances for Use in Compounding May Present Significant Safety Risks. <https://www.fda.gov/drugs/human-drug-compounding/certain-bulk-drug-substances-use-compounding-may-present-significant-safety-risks>

FDA. Clinical Pharmacology Considerations for Peptide Drug Products. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-pharmacology-considerations-peptide-drug-products>