ONIN IV Ondansetron (Zofran) SOP

Pregnancy and Lactation

Version:	Draft 1.0 (November 2025)
Approved by:	ONIN Clinical Standards Committee
Applies to:	Naturopathic Doctors providing IV therapy under prescribing authority or delegation

Rationale

Severe nausea and vomiting of pregnancy (NVP) and hyperemesis gravidarum (HG) can lead to maternal dehydration, malnutrition, and electrolyte imbalance, often requiring ER visits and hospitalization. If untreated, this can result in long-term maternal impacts such as nutrient deficiencies and mental health effects, as well as fetal risks such as low birth weight, preterm birth, and developmental concerns. IV administration of ondansetron may be considered when first-line therapies have failed, or oral tolerance is poor.

Ondansetron is a selective 5-HT■ receptor antagonist with strong evidence supporting its use in moderate-to-severe NVP/HG beyond the first trimester. Its safety profile in pregnancy is well established when used after 10 weeks gestation.

Approved Clinical Indications for IV Use

- Moderate to severe nausea and vomiting of pregnancy **after 10 weeks gestation** when oral or sublingual administration is not tolerated.
- Hyperemesis gravidarum unresponsive to first-line treatment (dietary modification, pyridoxine, doxylamine, hydration, dimenhydrinate, diphenhydramine).
- Prevention of dehydration or metabolic disturbance secondary to severe nausea and/or persistent emesis.

Contraindications

- Hypersensitivity to ondansetron or any component of the formulation.
- Long QT syndrome.
- Concomitant use with apomorphine or other QT-prolonging medications (e.g., certain SSRIs, macrolides, antipsychotics).
- Severe hepatic impairment (unless directed by pharmacist or NP with adjusted dosing).

Cautions

Use with caution in patients with:

- Electrolyte abnormalities (hypokalemia, hypomagnesemia, hyponatremia).
- Cardiac conduction disorders or concurrent use of medications known to prolong QT interval.
- History of serotonin syndrome or concomitant use of serotonergic agents (e.g., SSRIs, SNRIs, triptans).
- Early pregnancy (<10 weeks gestation); consult with OB/midwife or primary care provider before use.

Dosing and Administration

Standard Dose:

- **Ondansetron 4–8 mg PO/IV q8h as needed.**

- **Do not exceed 16 mg in a single dose.**
- **Do not exceed 8 mg total daily** in patients with hepatic impairment; consult pharmacist or NP for dosing verification.

IV Administration:

- Administer as **slow IV push over 2–5 minutes** or **diluted in 50 mL 0.9% NaCl and infused over 15–30 minutes.**
- No specific carrier required; maintain isotonicity when combined with other IV nutrients.
- Do **not** co-administer in the same line with calcium or magnesium salts.

Frequency: Every 8 hours as needed, based on severity of symptoms and patient tolerance.

Discontinuation: Wean patients slowly over 2 weeks when symptoms are minimal and patients have been able to maintain adequate oral intake and hydration for more than 2 weeks.

Monitoring During Treatment

Pre-Treatment:

- Review medical and obstetric history, medication list, and ECG if cardiac risk factors present.
- Check baseline electrolytes (Na, K, Mg, Ca).

During Infusion:

- Monitor for bradycardia, hypotension, dizziness, flushing, or local irritation.
- Observe patient for a minimum of 10 minutes post-administration.

Post-Treatment:

- Document patient response, degree of symptom relief, and any adverse reactions.
- Reassess hydration status and ability to tolerate oral fluids.

Adverse Reactions

Most common: mild headache, constipation, transient dizziness, flushing.

Less common: QT prolongation, bradycardia, hypersensitivity (rash, urticaria, bronchospasm).

■ **ALERT:** If chest pain, palpitations, or syncope occur, **stop infusion immediately**, assess vitals, perform ECG if available, and **escalate to emergency services.**

Escalation and Referral

If the following occur, refer to the patient's OB/midwife or emergency department:

- Inability to maintain oral intake or persistent vomiting >48 hours despite IV therapy.
- Evidence of dehydration or ketonuria not resolving with IV fluids.
- Recurrent vomiting associated with weight loss >5% of pre-pregnancy weight.
- Any cardiac abnormalities, severe hypotension, or suspected allergic reaction.

Special Considerations in Pregnancy and Lactation

- Ondansetron may be used **after 10 weeks gestation** with provider collaboration.
- Discuss with the primary care provider before initiating in early pregnancy.
- During lactation, monitor infant for irritability or feeding changes; limited data suggest low transfer to breastmilk.

- For patients requiring ongoing support, consider transition to oral therapy or supervised in-home infusion with pump setup per ONIN guidelines.

Documentation Requirements

- Record dose, route, time, and rate of administration.
- Record pre- and post-infusion vitals, symptom rating, and patient tolerance.
- Document patient education, informed consent, and communication with circle of care (OB/midwife/primary provider).
- Report any adverse reactions as per ONIN Adverse Event Reporting Policy.

Treatment Algorithm

NVP / Hyperemesis Gravidarum — Step-Based Management

Step 1 — Mild NVP

PUQE-24: 3–6 | HELP: 0–10

- B6/Pyridoxine 10–25 mg PO with or without Doxylamine 10–25 mg q6–8h (separately or as delayed-release combination)
- Thiamin/Benfotiamine 100 mg PO 1–3 times per day (250 mg daily minimum after 20 weeks)
- Continue prenatal vitamin if tolerated or change to single vitamins (B1, B9, D with K, Ca, Mg)
- Add gastric/esophageal protection at bedtime with onset of vomiting or poor intake

Step 2 — Moderate NVP

PUQE-24: 7–12 | HELP: 11–20

- Continue B6/doxylamine
- Add Antihistamine: Dimenhydrinate 25–50 mg PO q4–6h or Diphenhydramine 25–50 mg PO q6h
- OR Dopamine antagonist: Metoclopramide 5–10 mg PO/IV q6–8h
- Consider Ondansetron 4–8 mg PO q8h if refractory to above
- Hydration: Oral rehydration solutions or 1–2 L IV normal saline with thiamine 100 mg
- Electrolyte repletion: Add KCl/Mg as indicated; Follow-up: 3–5 days or earlier if no improvement

Step 3 — Severe / Hyperemesis Gravidarum

PUQE-24: ≥13 | HELP: ≥21

- IV: Normal saline ± thiamine 100 mg IV; add electrolytes as needed
- Ondansetron 4–8 mg IV q8h (may transition to PO/ODT once tolerated)
- Add or alternate: Metoclopramide 10 mg IV q8h or Dimenhydrinate 50 mg IV q6h
- Nutrient Support: IV B-complex, Magnesium, Vitamin C as tolerated
- Iron/Copper deferred until second trimester or unless deficient

Step 4 — Refractory or Complicated HG

Persistent vomiting, severe malnutrition, or abnormal labs despite above

- Hospital admission; OB/Gyne + dietitian + mental health collaboration
- Consider IV Zofran pump or home IV therapy
- Monitor for Wernicke's, electrolyte imbalance, and fetal growth
- Consider Corticosteroids (e.g., Methylprednisolone 16 mg q8h × 3 days, then taper) after 10 weeks gestation
- Enteral (NG/NJ) or Parenteral nutrition if prolonged poor intake (>10 days)
- Consider thromboprophylaxis if immobilized or on PN