# Revestive▼ (teduglutide): How to prepare and support your adult patients with SBS-IF

## Your practical guide for selecting appropriate adult patients and supporting them during Revestive treatment

Revestive is indicated for the treatment of patients 4 months corrected gestational age and above with Short Bowel Syndrome (SBS). Patients should be stable following a period of intestinal adaptation after surgery.[1]

Takeda

Prescribing information for the United Kingdom can be found by scanning this QR code or clicking this link.

C-APROM/GB/REV/0279 | March 2025

**Adverse events should be reported. Reporting forms and information can be found at: www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Takeda at: AE.GBR-IRL@takeda.com**

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# Identify and evaluate appropriate patients

You can determine the appropriateness of Revestive by evaluating key patient characteristics.[1,2]

## Eligibility requirements:[1]

- Patients must be aged 4 months or above with SBS-IF
- Patients should be stable after a period of intestinal adaptation following surgery
- PN/IV intake should be optimised and stabilised

Carefully review the contraindications, special warnings and precautions for each patient,[1] refer to SmPC for further details

## Remember the basics when considering patients for Revestive:[1,2]

### Contraindications

- **Revestive is contraindicated in patients with:**
  - Hypersensitivity to the active substance or to the excipients, or trace residues of tetracycline
  - Active or suspected malignancy
  - A history of malignancies in the GI tract, including the hepatobiliary system and pancreas within the last five years

### PN/IV requirements*

- **Patient should be dependent on PN/IV, despite:**
  - Optimised dietary modifications
  - Adjunctive medications
- **Patient is motivated to reduce or discontinue PN/IV**

### Nutrients and fluids considerations*

- **Patient should be nutritionally optimised and in fluid balance as assessed by:**
  - Realistic target body weight
  - Serum albumin status
  - Blood urea nitrogen/creatinine ratio
  - Vitamin status
  - Mineral status

Treatment should be initiated under the supervision of a medical professional with experience in the treatment of SBS

*Best practice recommendation from Seidner DL, et al. J Parenter Enteral Nutr 2013.
GI, gastrointestinal; PN/IV, parenteral nutrition/intravenous fluids; SBS, short bowel syndrome; SBS-IF, short bowel syndrome with intestinal failure; SmPC, summary of product characteristics.

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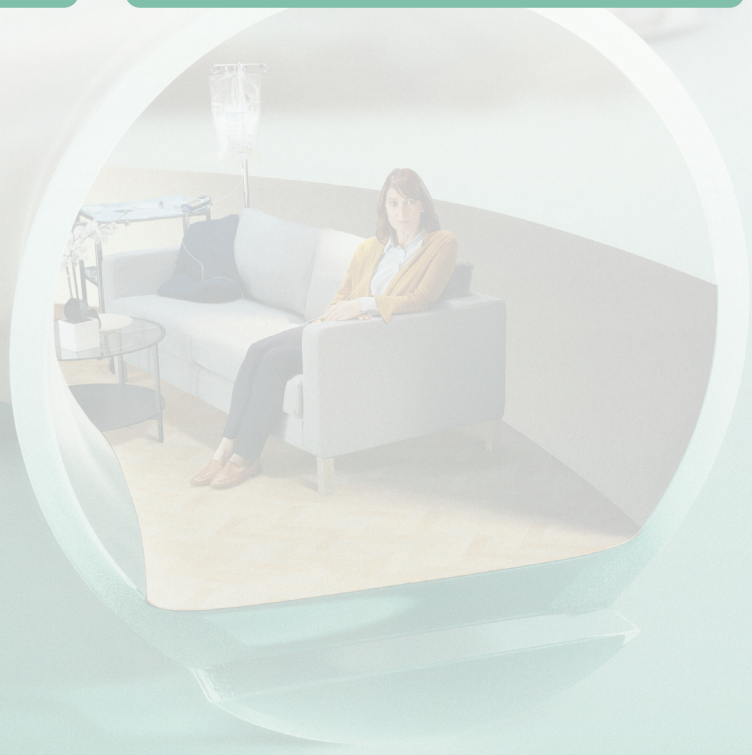
# Set your patients expectations

Help your patients to understand the processes, potential benefits and risks associated with Revestive treatment.

Processes

Benefits

Risks



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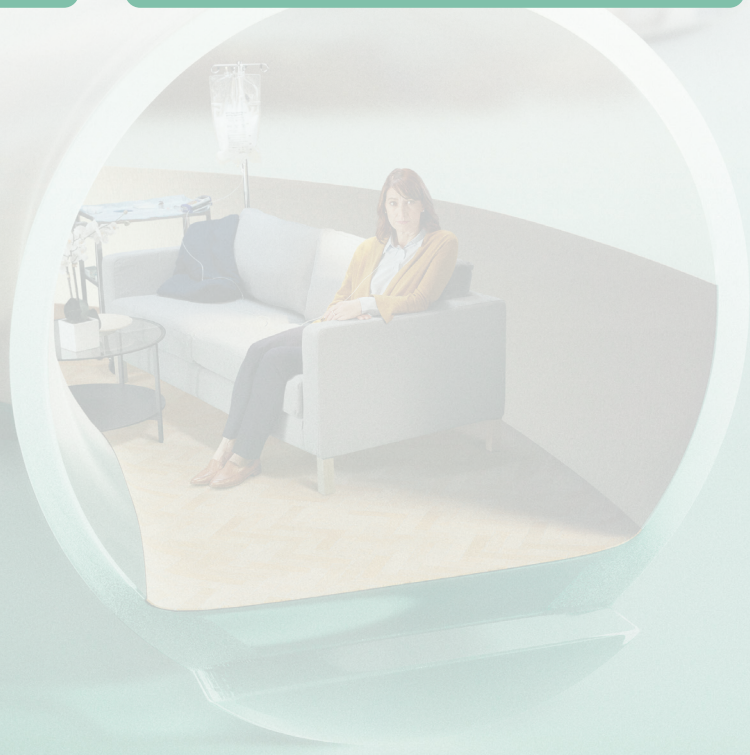

### Highlight the need for regular monitoring

All patients on long-term PN/IV need regular monitoring to assess nutrient balance and liver function.[2] When receiving Revestive, additional monitoring is required when adjusting the volume of PN/IV.[2]

### Explain how weaning strategies can differ

There are two methods which may be used to wean patients from PN/IV – reducing the volume of PN/IV per day, or reducing the number of days per week.[2,3] The method and speed of reduction will depend on each patient's response to Revestive and their needs.[2,3]

### Set their expectations for treatment duration

Treatment with Revestive is recommended to continue, even in patients who have completely weaned off PN/IV.[1]

### Educate your patients on the homecare service

Your patients may receive their medication and injections at home and be trained to self-inject.

**Click here for more information regarding homecare**

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PN/IV, parenteral nutrition/intravenous fluids.

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## Benefits

### Inform your patients that they could experience less need for or complete freedom from PN/IV[4,5]

In clinical studies, up to 89% of patients who received Revestive were able to reduce their PN/IV volume requirements.[4,5*] Compared to PN/IV alone, a significant number (n=21/30 [70%] vs n=3/6 [50%] with placebo) reduced their needs by one day or more per week, and 33% of patients managed to achieve complete freedom from PN/IV at 30 months.[5*]

### Remind your patients on the importance of persistence

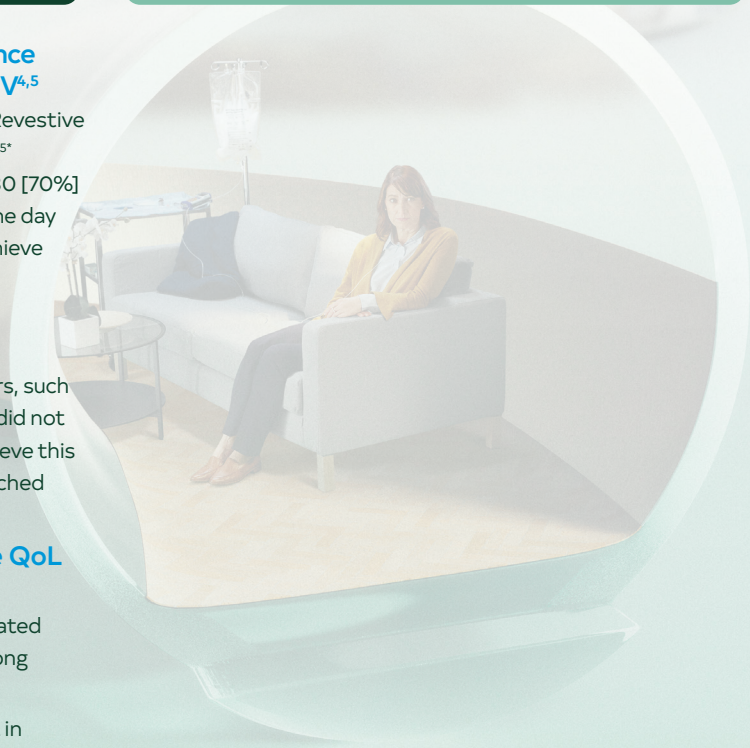
Results occur over time, and may vary by patient factors, such as bowel anatomy.[5,6*†] Seven of the eight patients who did not respond (≥20% PN/IV reduction) at six months did achieve this within 30 months of treatment, and three of those reached complete freedom from PN/IV.[5*]

### Tell your patients that they may experience QoL improvements with Revestive[7‡]

A reduction of a single day off PN/IV per week is associated with a statistically significant improvement in QoL among patients with SBS-IF.[8,9]

Revestive has been shown to significantly improve QoL in SBS-IF patients vs PN alone.[7‡] Patients who require large volumes of PN/IV when starting treatment or have SBS-IF due to IBD may experience the most QoL benefit.[10§]

## Risks



*Based on two studies: a 24-week randomised, double-blind, placebo-controlled, Phase 3 study of adult patients with SBS-IF and at least 12 months of continuous PN and/or IV dependency (PN/IV required ≥3 times per week) (Revestive 0.05 mg/kg/day, n=43; placebo, n=43); and the two-year open-label extension where patients who completed the 24-week study receiving Revestive, placebo, or were not treated, received Revestive 0.05 mg/kg/day for up to 30 total months (N=88); †Post-hoc analysis of the 24-week study investigating patient factors associated with response to Revestive (N=85); ‡Based on a multicentre, observational study in a French adult cohort of the SBS-IF registry comparing change in SBS-QoL scores in 48 propensity score matched patients from baseline (after ≥6 months of PN) to after ≥6 months of Revestive or ≥6 months of continued PN without Revestive; §Post-hoc analysis of the 24-week study investigating change in SBS-QoL scores from baseline (N=86).

IBD, inflammatory bowel disease; PN, parenteral nutrition; PN/IV, parenteral nutrition/intravenous fluids; QoL, quality of life; SBS-IF, short bowel syndrome with intestinal failure; SBS-QoL, Short Bowel Syndrome-Quality of Life.

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## Risks

### Ensure your patients are aware of potential adverse effects with Revestive[1]

In 109 patients across two clinical studies lasting up to 24 weeks, approximately 52% of patients who received Revestive experienced an adverse reaction.[1] The most commonly reported adverse reactions were abdominal pain and distention (45%), respiratory tract infection (28%), nausea (26%), injection site reactions (26%), headache (16%), and vomiting (14%).[1] In patients who had a stoma, approximately 38% experienced gastrointestinal stoma complications.[1] The majority of these reactions were mild or moderate in severity.[1]

### Discuss the risks of Revestive treatment

As Revestive can increase intestinal absorption, fluid overload is a risk that needs to be monitored.[1] Stopping Revestive needs to be carefully managed due to risk of dehydration.[1]

### Prepare your patients to report any adverse reactions or sudden changes

Potential sudden changes which should be reported include weight gain, swollen face, swollen ankles and/or breathlessness, which may indicate fluid overload.[1] Rapid changes in urine output should also be reported.[2]

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# Prepare for dosing and administration

Revestive requires weight-based dosing at 0.05 mg/kg once daily by subcutaneous injection.[1]

## Adult weight-based dosing[1*]

| Body weight | **5 mg strength** Volume to be injected |
|---|---|
| 38–41 kg | 0.20 mL |
| 42–45 kg | 0.22 mL |
| 46–49 kg | 0.24 mL |
| 50–53 kg | 0.26 mL |
| 54–57 kg | 0.28 mL |
| 58–61 kg | 0.30 mL |
| 62–65 kg | 0.32 mL |
| 66–69 kg | 0.34 mL |
| 70–73 kg | 0.36 mL |
| 74–77 kg | 0.38 mL |
| 78–81 kg | 0.40 mL |
| 82–85 kg | 0.42 mL |
| 86–89 kg | 0.44 mL |
| 90–93 kg | 0.46 mL |

- **The reconstituted solution should be administered by subcutaneous injection once daily, alternating sites between the four quadrants of the abdomen[1]**
- **The thigh can also be used if injection in the abdomen is difficult because of pain, scarring, or hardening of the tissue[1]**
- **Revestive should not be administered by intravenous or intramuscular routes[1]**
- **If a dose is missed, that dose should be injected as soon as possible on that day[1]**

*In patients with moderate or severe renal impairment (creatinine clearance of less than 50 mL/min) or end-stage renal disease, the daily dose of Revestive must be reduced by 50% and carefully monitored.[1]

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# Educate your patients on the Revestive homecare service

You can prepare your patients for home injections with key information and resources.

**Takeda provides a fully funded comprehensive homecare service, delivered either by Sciensus or HealthNet.* This service includes a fully qualified nurse meeting with you or your patient(s) in the hospital, providing training in your patient's home, and monitoring of patients and sharing feedback to the hospital team.**

## Ancillaries for Revestive

The below list includes the ancillary items specific to Revestive, which are provided by the homecare company to patients with their 4-weekly deliveries:

| Ancillary items | Units provided |
|---|---|
| Reconstitution needle (22 gauge)/ Green needle | 28 (one/vial) |
| Administration (s/c) needle (25 G to 30 G) | 28 |
| 0.5 ml/1 ml syringes | 28 |
| Sharps bin (5 L/ 11 L/ 22 L) as requested | 1 |
| Alcohol swabs | 56 |
| Travel sharps bin (as required) | 1 (when requested) |
| Wipes — small | 1 pack first delivery, then as required |

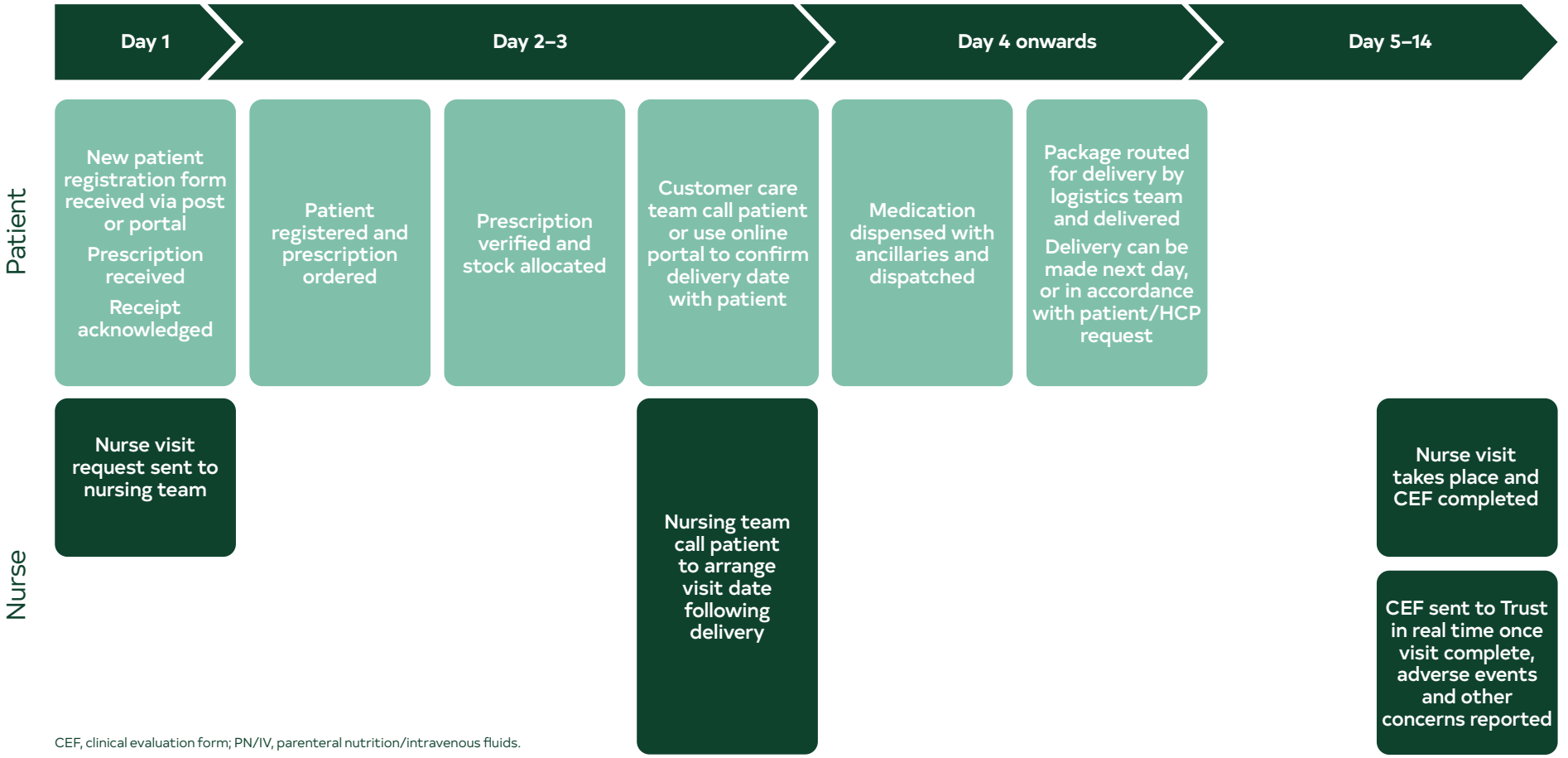
## Patient pathway

| Year 1 | Number provided |
|---|---|
| **Deliveries in Y1 (4 weekly)** | **14** |
| Initial nurse meeting with patient in hospital | 1 |
| Initial nurse visit with patient at home (wk1; day 1) | 1 |
| Initial nurse visit with patient at home (wk1; day 1) *Second visit possible* | 1 |
| Nurse visits (wk 2, 3, 4; once per week) | 3 |
| Nurse visits (wk 6, 8, 10, 12; once per week) | 4 |
| Nurse visits (wk 16, 20, 24; once per week) *Followed by hospital review* | 3 |
| Nurse visits (wk 35, 43, 51; once per week) | 3 |
| **Subtotal of nurse visits in Y1** | **16** |
| **Outgoing field nurse phone calls Y1 24 hours after nurse visit** | **12** |
| Year 2 | |
| **Deliveries in Y2 (4 weekly)** | **12** |
| **Nurse visits (quarterly) With nurse phone call min. 3 working days beforehand** | **4** |

Click here to view the homecare patient referral pathway

*Ancillaries for Revestive, patient pathway and patient referral pathway may differ between homecare companies.
min, minimum; s/c, subcutaenous; wk, week; y, year.

## Homecare Patient Referral Pathway




CEF, clinical evaluation form; PN/IV, parenteral nutrition/intravenous fluids.

Click here to view the homecare patient referral pathway

# Keep in touch with your patients changing needs

Follow-up appointments, laboratory tests, and patient diaries can support the PN/IV weaning process.[2]

## As the intestine adapts and absorbs more liquids and nutrients, the requirement for PN/IV should start to decrease[2]

- This could be reflected by increased urine output or gradual weight gain, despite stable PN/IV intake[2]
- Monitoring changes in 48-hour urine volume with consistent oral fluid intake can help to inform when to adjust PN/IV[2,4]
- PN/IV reduction could be done by decreasing daily volume of PN/IV, or reducing days on PN/IV (starting with non-consecutive days off)[2,3]
- The below algorithm may be a useful guide, combined with your clinical judgement, based on the response time and health status of each patient[4]

| URINE OUTPUT | PN/IV ADJUSTMENTS |
|---|---|
| <1.0 L/day or target based on stabilised urine output | Increase PN/IV by ≥10% (from Week 2) or to previous level |
| ≥1.0 L/day but less than baseline* | If patient is dehydrated or inadequately nourished, increase PN/IV. If not, maintain PN/IV |
| 0% to <10% increase over baseline* | Maintain PN/IV |
| ≥10% increase over baseline* | Reduce PN/IV by ≥10% of stabilised baseline level up to a clinically appropriate amount (maximum of 30%) |

## Recommend a diary to your patients

- **Tracking their progress with a diary may help your patients take an active role in their treatment and guide important clinical decisions**
- **The patient diary should capture:[2]**
  - Weight
  - Actual (not prescribed) PN/IV intake
  - Oral food intake
  - Oral fluid intake
  - Urine output
  - Stool/ostomy output
  - Side effects, which patients should also be advised to report to their medical team immediately
- **It is recommended that you review and discuss the diary data with your patient at each appointment[2]**
- **Remind your patients to bring their diary to every consultation, whether face to face or digital**

**Please email uk.sbs.if@takeda.com to receive a copy of a treatment diary to support your patients**

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*Baseline is the urine volume output achieved at the end of the stabilisation period before initiating treatment.
PV/IV, parenteral nutrition/intravenous fluids.

# Remember these patient monitoring suggestions[1,2,11]

Stay on top of patient monitoring with the Revestive treatment follow-up checklist.[1,2,11]

| INVESTIGATION | Initiation | Weeks 2 & 4 | Depending on PN/IV stability: Q1W if PN/IV adjusted | Depending on PN/IV stability: Q4W if PN/IV adjusted | Depending on PN/IV stability: Q12–16W if PN/IV stable | 6 to 12 months | Every year |
|---|---|---|---|---|---|---|---|
| Consultation/review | • | • | | | • | | |
| PN/IV intake (mandatory) | • | • | • | OR† • | • | | |
| Body weight | • | • | • | OR† • | • | | |
| Urine output | • | • | • | OR† • | • | | |
| Stoma/stool output | • | • | • | OR† • | • | | |
| Serum/urine electrolytes & minerals‡ (mandatory) | • | • | • | OR† • | • | | |
| Serum urea, creatinine, glucose, bicarbonates | • | • | • | OR† • | • | | |
| C-reactive protein | • | • | • | OR† • | • | | |
| Full blood count | • | • | • | OR† • | • | | |
| Liver function tests | • | • | | • | • | | |
| Serum folate, vitamins D, B12, A, E | • | | | • | | • | |
| Serum albumin and prealbumin | • | | | • | • | | |
| Serum zinc, copper, selenium | • | | | | | • | |
| Serum ferritin iron | | | | | • | | |
| Serum manganese | • | | | | | | • |
| Colonoscopy (mandatory)* | • | | | | | | •¶ |
| Liver ultrasound | • | | | | | | • |
| Bone density scan | • | | | | | | • |

HPN, home parenteral nutrition; Q1W, every week; Q4W, every 4 weeks; Q12–16W, every 12 to 16 weeks; PN/IV, parenteral nutrition/intravenous fluids.

Clinical assessment by the physician should consider individual treatment objectives and patient preferences. Treatment should be stopped if no overall improvement of the patient condition is achieved. Efficacy and safety in all patients should be closely monitored on an ongoing basis according to clinical treatment guidelines.[1]

Patients on long-term PN/IV require regular monitoring of renal and liver function, nutritional status, electrolytes and fluids.[2] As patients become more independent from PN/IV, special attention should be given to monitoring the levels of vitamins and minerals.[2] Oral supplementation of micronutrients, particularly potassium and magnesium, is often necessary.[2]

Revestive treatment effect should be evaluated at 6 and 12 months.[1]

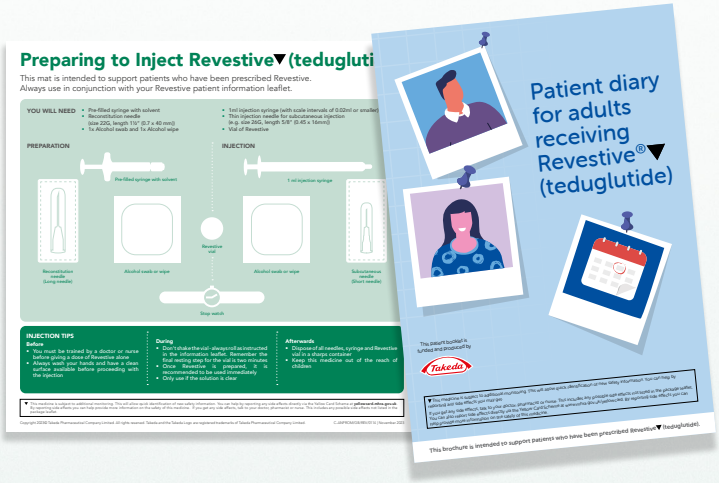
This list is not exhaustive. For a full list of monitoring recommendations for patients on PN/IV, see the ESPEN guideline on HPN (2020).[11]

*Upper gastrointestinal endoscopy or other imaging is recommended before and during treatment with Revestive; †Monitoring frequency is recommended as every one or four weeks, based on the patient's general condition and the clinician's discretion; ‡Includes sodium, chlorine, potassium, magnesium, calcium, and phosphorus; ¶Colonoscopy is recommended at initiation with removal of any polyps, and yearly for the first two years of treatment, with a minimum of 5-year-follow-up thereafter.

# Find further support for Revestive treatment

## Additional resources for you and your team:


## Additional resources for your patients:




**For further information or materials (e.g., patient diaries) please email uk.sbs.if@takeda.com**


1. Revestive (teduglutide) Summary of Product Characteristics; 2. Seidner DL, et al. *J Parenter Enteral Nutr* 2013;37:201–211; 3. DiBaise JK, et al. *J Clin Gastroenterol* 2006;40(suppl 2):S94–S98; 4. Jeppesen PB, et al. *Gastroenterology* 2012;143:1473–1481; 5. Schwartz LK, et al. *Clin Transl Gastroenterol* 2016;7:e142; 6. Jeppesen PB, et al. *Gastroenterol* 2018;154:874–885; 7. Joly F, et al. *Clin Nutr ESPEN* 2021;46:PS665; 8. Ballinger R, et al. *Clin Ther* 2018;40:1878–1893.e1; 9. Lachaine J, et al. *Value Health* 2016;19:A251; 10. Chen K, et al. *J Parenter Enteral Nutr* 2020;44:119–128; 11. Pironi L, et al. *Clin Nutr* 2020;39:1645–66.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