Revestive▼ (teduglutide):

Initiation and management of treatment in children and adolescent patients (aged 4 months to 17 years)

Your guide to identifying appropriate paediatric patients, starting treatment, and managing the Revestive journey

Takeda

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]

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

C-APROM/GB/REV/0281 | 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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How to Use This Guide

Use this guide to help manage the treatment of your child and adolescent patients with SBS-IF, working closely with their caregiver(s) as they begin treatment.[1]

Useful identification criteria and considerations have been provided along with helpful tips on how to communicate with your patients and their caregiver(s) about what to expect throughout treatment. The PN/IV weaning algorithm will help you determine how and when to reduce PN/IV and what to look for during follow-up visits.

Remember, the care of all patients on Revestive requires frequent monitoring and must be flexible and respond to the needs of both the patient and their healthcare team.

Note: This guide does not replace the SmPC. For more information, please refer to the SmPC.

PN/IV, parenteral nutrition/intravenous fluids; SBS-IF, short bowel syndrome with intestinal failure; SmPC, Summary of Product Characteristics.

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PN/IV, parenteral nutrition/intravenous fluids.

Patient Identification

Learn how to start eligible patients on Revestive treatment. Review all eligibility criteria and clinical tests when considering new patients.

Eligibility requirements[1]

Review the Revestive SmPC before prescribing.

- **Patients must be aged 4 months corrected gestational age and above with SBS**
- **Patient should be stable following a period of intestinal adaptation after surgery**
- **PN/IV intake should be optimised and stabilised**

PN/IV, parenteral nutrition/intravenous fluids; SBS, short bowel syndrome; SmPC, summary of product characteristics.

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Contraindications[1]

Check for the absence of contraindications, which are:

- Hypersensitivity to the active substance or to any of the excipients listed below, or trace residues of tetracycline
  - L-histidine, mannitol, sodium phosphate monohydrate, disodium phosphate heptahydrate, sodium hydroxide (pH adjustment)*, hydrochloric acid (pH adjustment)*
- Active or suspected malignancy
- A history of malignancies in the gastrointestinal tract, including the hepatobiliary system and pancreas, within the last 5 years

Check that the PN/IV and clinical status are stable[1]

Treatment should not be initiated until it is reasonable to assume that the patient is stable following a period of intestinal adaptation. Optimisation and stabilisation of PN/IV should be performed before initiation of treatment.

*Applies only to 5 mg dose of Revestive (teduglutide).
For more information refer to the Summary of Product Characteristics.
PN/IV, parenteral nutrition/intravenous fluids.

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How to identify patients who may benefit from Revestive

Precautions and clinical considerations[1]

Carefully review the contraindications, special warnings and precautions for each patient. Please refer to the SmPC for further details

Special warnings and precautions for use:

- Colo-rectal polyps/neoplasia
  - Colonoscopy/sigmoidoscopy is recommended for all children or adolescents after one year of treatment, every 5 years thereafter while on continuous treatment with Revestive, and if they have new or unexplained gastrointestinal bleeding
- Gastrointestinal neoplasia including hepatobiliary tract
  - Upper gastrointestinal endoscopy or other imaging is recommended before and during treatment with Revestive
- Gallbladder or bile duct disease
- Monitoring of small bowel, gallbladder and bile ducts, and pancreas
  - Patients should be kept under close surveillance including monitoring of small bowel function, gallbladder and bile ducts, and pancreas for signs and symptoms, and, if indicated, additional laboratory investigations and appropriate imaging techniques
- Pancreatic disease
- Intestinal obstruction
- Fluid overload and electrolyte balance
  - Due to increased fluid absorption, patients with cardiovascular disease, such as cardiac insufficiency and hypertension, should be monitored with regard to fluid overload
- Dehydration
- Concomitant medical products
- Severe, clinically unstable concomitant diseases (such as cardiovascular, respiratory, renal, hepatic, endocrine, infectious, or central nervous system)
- Hepatic impairment
- Patients with malignancies within the last 5 years
- Discontinuation of treatment

Prior to initiating treatment with Revestive, faecal occult blood testing should be done for all children and adolescents[1]

– Colonoscopy/sigmoidoscopy is required if there is evidence of unexplained blood in the stool

After initial faecal occult blood testing, subsequent testing should be performed annually during treatment with Revestive

SmPC, summary of product characteristics.

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Additional considerations based on expert opinion[1,2]

- Patient should only receive Revestive after assessment and discussion among multidisciplinary team members
- Patient and caregiver are aware that Revestive is a daily injection and are motivated to learn how to properly administer the medication

Remember the basics when considering patients for Revestive

CLINICAL STATUS AND MONITORING CONSIDERATIONS*

Stable[1]

No intestinal obstruction[1]

No cardiovascular disease[1]

No small bowel, gallbladder, biliary tract and pancreatic diseases[1]

No malignant disease[1]

PN/IV REQUIREMENTS

Dependent on PN/IV despite:[2]

- Optimised dietary modifications
- Adjunctive medications

Unsuccessful attempts or complications when weaning from PN/IV in the past

NUTRIENTS AND FLUIDS

Nutritionally optimised and in fluid balance as assessed by:[2]

- Realistic target body weight
- Maintenance of normal growth
- Serum albumin status
- BUN/creatinine ratio
- Vitamin status
- Mineral status

ACTIVE ROLE IN MANAGEMENT

Patient and caregiver are motivated to reduce or discontinue the use of PN/IV[2†]

Patient has the ability to and both the caregiver and patient have the will to increase oral nutrition to compensate for PN/IV volume reduction[2]

Patient and caregiver agree to monitor required inputs and outputs[2]

*Please refer to the Summary of Product Characteristics for information about contraindications. †Best practice recommendation.
BUN, blood urea nitrogen; PN/IV, parenteral nutrition/intravenous fluids.

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Starting Revestive

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

Before initiating Revestive, patients should undergo several laboratory tests and clinical assessments. During this time, it is important to communicate openly with your patient and their caregiver(s). Make sure they fully understand the implications of treatment.

Laboratory tests and clinical assessments*

Monitoring treatment with Revestive:

Clinical and nutritional assessment[1-4]

- Body weight
- Body length/height
- Head circumference for patients younger than 3 years of age
- Dietetic consultation to assess food intake (kcal or kJ) and nutrient content

Blood tests[2]

- Electrolytes (sodium, potassium, chloride, bicarbonate, calcium, phosphate, magnesium)
- BUN
- Creatinine
- Liver function tests
- Proteins

Additional tests[3†]

- Full blood count, platelets
- Vitamins (A, B12, folate, D, E)
- Trace elements (zinc, copper, selenium)
- Iron status
- Albumin
- Blood glucose

*Best practice recommendations.

†Based on recommendations from ESPGHAN/ESPEN/ESPR/CSPEN guidelines. This recommendation is not specific to Revestive.

BUN, blood urea nitrogen; SBS, short bowel syndrome.

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Urinalysis[2,3]

- Urine output (24- to 48-hour measure, if possible)

Hydration status may be assessed using surrogate markers, such as urine-specific gravity and/or urine sodium, in patients for whom a 24- to 48-hour urine output measure may be difficult (e.g., patients in school, working caregivers, etc).

Stool assessment[2]

- Baseline stool frequency, quantity, and consistency
- Stoma output (if stoma present) measured by the number of times the stoma bag is emptied
- Stool electrolytes (sodium, potassium)

Other investigations[1]

- Faecal occult blood testing to assess colorectal polyps/ neoplasia

Concomitant medication[1]

- As a result of increased absorption, there is a risk of toxicity

Communication with the patient and their caregiver(s)

Communicate openly with your patient and their caregiver(s) and emphasise the importance of support throughout the Revestive journey

Inform the patient and their caregiver(s) to ensure they fully understand the requirements associated with Revestive[1,6]

- Explain the effects of treatment and discuss the goals
- For patients with an intact colon, inform the patient and their caregiver(s) about the preinclusion procedures that may include colonoscopy, and the surveillance strategy for polyps
  - Upper gastrointestinal endoscopy or other imaging is recommended before and during treatment with Revestive
- Remind them that it is imperative to report adverse events to their doctor and/or nurse
- The caregiver(s) must be fully trained on how to administer and monitor Revestive
  - Ensure the caregiver(s) has been well trained in the injection technique and is aware that Revestive requires daily administration
- The caregiver(s) must be aware that frequent monitoring may disrupt a previously established routine
- The caregiver(s) must be aware that an increase in oral feeding will be required after the patient begins to wean from PN/IV

The patient and their caregiver(s) should receive input/support from a multidisciplinary team to ensure they are aware of the requirements needed to manage a paediatric patient with SBS-IF on Revestive.[2]

For a patient with a stoma, inform them about the possibility of stoma nipple size enlargement and how to adjust and enlarge the hole in the stoma pad.[6]

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PN/IV, parenteral nutrition/intravenous fluids; SBS-IF, short bowel syndrome with intestinal failure.

Ensure the patient and their caregiver(s) fully understand the potential benefits and risks associated with Revestive treatment[1,2,5]

Topics of discussion should include:

- Information on the probability of reducing the need for or weaning from PN/IV
- Difference in weaning strategy (less frequent vs reduced volume)
- Probability of quality of life improvement
- Duration of treatment
- Potential adverse effects and risks of the treatment
- Need to undergo careful and regular monitoring
- Adequate training and information on the injection technique (which could minimise injection site reactions)

There are 3 potential outcomes relating to PN/IV reduction

- Hours off of PN/IV
- Days off of PN/IV
- Complete independence from PN/IV

Warnings and precautions[1]

- Fluid overload and electrolyte balance
- Intestinal obstruction
- Biliary and pancreatic disease
- Potential to increase absorption of concomitant oral medicinal products requiring titration or with a narrow therapeutic index
- Neoplastic growth

Overall, the safety profile of Revestive (including type and frequency of adverse reactions) in children and adolescents (aged 1–17 years) was similar to that in adults.

PN/IV, parenteral nutrition/intravenous fluids.

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Dosing and administration

Learn about Revestive weight-based dosing and subcutaneous injection

Calculating the dose of Revestive[1]

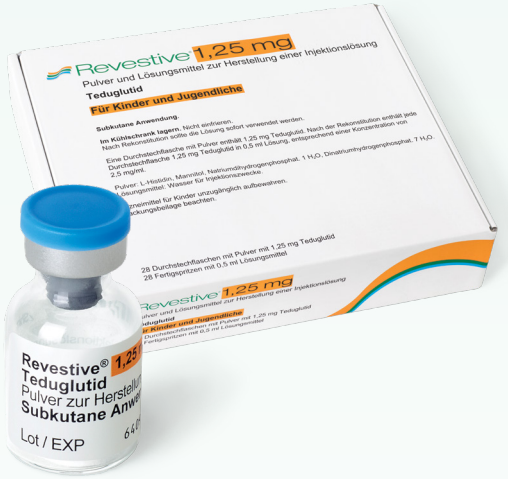
- Daily dosage: 0.05 mg/kg once a day
- Volume to inject according to body weight

Revestive is available in a 1.25 mg and 5 mg strength vial. For paediatric patients who weigh >20 kg, the 5 mg strength vial should be used.

Dosing for 1.25 mg strength vial[1]

BODY WEIGHT	VOLUME TO BE INJECTED
5–6 kg	0.10 mL
7–8 kg	0.14 mL
9–10 kg	0.18 mL
11–12 kg	0.22 mL
13–14 kg	0.26 mL
15–16 kg	0.30 mL
17–18 kg	0.34 mL
19–20 kg	0.38 mL
>20 kg	Use the 5 mg strength vial

ESRD, end-stage renal disease.



Note: In patients with moderate or severe renal impairment (creatinine clearance <50 mL/min) or ESRD, the daily dose of Revestive must be reduced by 50% and carefully monitored.[1]

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Dosing for 5 mg strength vial[1]

BODY WEIGHT	VOLUME TO BE INJECTED
10–11 kg	0.05 mL
12–13 kg	0.06 mL
14–17 kg	0.08 mL
18–21 kg	0.10 mL
22–25 kg	0.12 mL
26–29 kg	0.14 mL
30–33 kg	0.16 mL
34–37 kg	0.18 mL
38–41 kg	0.20 mL
42–45 kg	0.22 mL
46–49 kg	0.24 mL

BODY WEIGHT	VOLUME TO BE INJECTED
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

Revestive administration[1]

- The reconstituted solution must be administered by subcutaneous injection once daily, alternating sites between the 4 quadrants of the abdomen
- The thighs can also be used if injection in the abdomen is difficult because of pain, scarring, or hardening of the tissue
- Revestive should not be administered by intravenous or intramuscular routes
- If a dose is missed, that dose should be injected as soon as possible on that day

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Common adverse events[1]

System Organ Class	Frequency	
	Very common (≥1/10)	**Common (≥1/100 to <1/10)**
Infections and infestations	Respiratory tract infection*	Influenza-like illness
Metabolism and nutrition disorders		Decreased appetite, fluid overload
Psychiatric disorders		Anxiety, insomnia
Nervous system disorders	Headache	
Cardiac disorders		Congestive heart failure
Respiratory, thoracic and mediastinal disorders		Cough, dyspnoea
Gastrointestinal disorders	Abdominal distension, abdominal pain, nausea, vomiting	Colorectal polyp, colonic stenosis, flatulence, intestinal obstruction, pancreatic duct stenosis, pancreatitis,† small intestinal stenosis
Hepatobiliary disorders		Cholecystitis, cholecystitis acute
General disorders and administration site conditions	Injection site reaction‡	Oedema peripheral
Injury, poisoning and procedural complications	Gastrointestinal stoma complication	

Refer to the Revestive Summary of Product Characteristics for a full list of adverse events.
All adverse reactions identified in post-marketing experience are italicised.

* Includes the following preferred terms: Nasopharyngitis, Influenza, Upper respiratory tract infection, and Lower respiratory tract infection.
† Includes the following preferred terms: Pancreatitis, *Pancreatitis acute*, and Pancreatitis chronic.
‡ Includes the following preferred terms: Injection site haematoma, Injection site erythema, Injection site pain, Injection site swelling and Injection site haemorrhage.

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Maintenance of Revestive

Learn how and when to adjust PN/IV and manage patients throughout their treatment journey. It is important that your patient and caregiver(s) keep a diary to record the necessary information for efficient weaning. Frequent monitoring is key to success and should be conducted at follow-up.[2]

PN/IV, parenteral nutrition/intravenous fluids.

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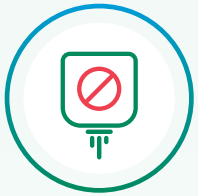
Guidance for PN/IV and nutritional adjustments

How to wean patients from PN/IV with Revestive



Suggested algorithm for PN/IV reduction[2,5,7]

No official guidelines have been published regarding the recommended approach for weaning patients from PN/IV. The algorithm suggested was used in the pivotal Phase 3 study in children and adolescents with SBS-IF.

As the intestine adapts and absorbs more liquids and nutrients, the requirement for PN/IV should start to decrease. This can be expressed in a variety of ways, including fluid intake exceeding output despite stable volumes of PN/IV and gradual weight increase despite stable PN/IV-calorie content.

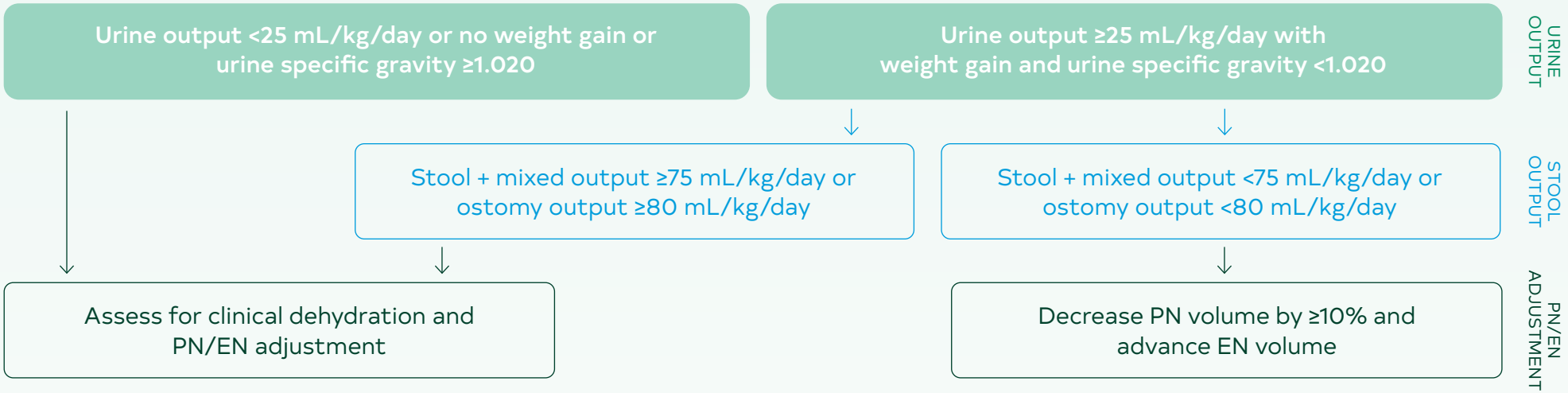
In clinical practice, this algorithm might be used as a guide, but you should also use your judgement based on the response time and the general health status of each patient. A nutritional care plan is dynamic, and ongoing support should reflect changes in nutritional and clinical status. ESPGHAN/ESPEN/ESPR/CSPEN guidelines on paediatric PN/IV suggest the process be overseen by a multidisciplinary nutrition team (eg, physician, nurse, dietician/nutritionist, pharmacist, etc).

After every PN/IV modification[7]

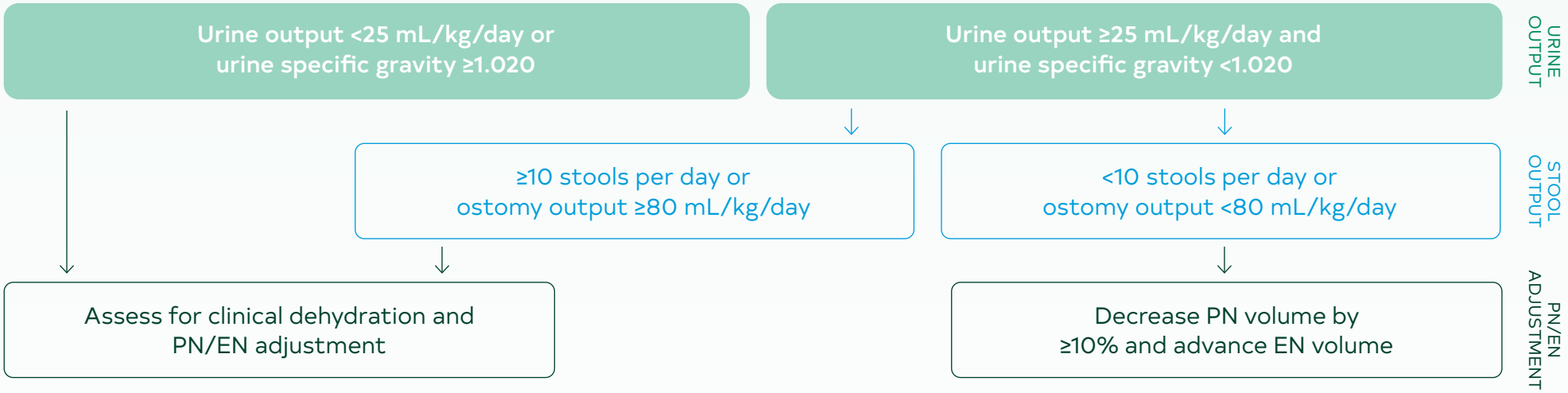
It is suggested to schedule regular consultations as appropriate until PN/IV is stabilised, in order to check maintenance of hydration and nutritional status.

CSPEN, Chinese Society of Parenteral and Enteral Nutrition; ESPEN, European Society for Clinical Nutrition and Metabolism; ESPGHAN, European Society for Paediatric Gastroenterology Hepatology and Nutrition; ESPR, European Society for Paediatric Research; PN/IV, parenteral nutrition/intravenous fluids; SBS-IF, short bowel syndrome with intestinal failure.

SUGGESTED WEANING ALGORITHM FOR PATIENTS WHO ARE *NOT* TOILET TRAINED AND IN NAPPIES[5]



SUGGESTED WEANING ALGORITHM FOR PATIENTS WHO ARE TOILET TRAINED AND *NOT* IN NAPPIES[5]



EN, enteral nutrition; PN, parenteral nutrition; PN/EN, parenteral/enteral nutrition.

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Patient follow-up

Achieve frequent monitoring through follow-up appointments, laboratory tests, and a patient diary

Patient diary[2]

Patient diaries should be designed to help your patient and their caregiver(s) record progress and help guide important treatment decisions, ensuring that your patients get the most from their experience with Revestive. If your patient is old enough, the patient diary helps them take an active role in their treatment. Diaries should be completed at least every week and especially within 48 hours before a consultation.

Diaries should capture the patient's:[1,2,5]

- Weight
- Actual PN/IV intake (may be different to prescribed amount)
- Daily oral food and fluid intake
- Daily urine volume
- Stool/ostomy output

Any new symptoms recorded by the patient or their caregiver(s) should be reported immediately to the treating medical team. Remind your patient and their caregiver(s) to bring their diary to every consultation or have it ready for each phone follow-up.

There should be an ongoing dialogue between HCPs and caregiver(s) between appointments.

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

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HCP, healthcare professional; PN/IV, parenteral nutrition/intravenous fluids.

Suggested follow-up plan based on expert opinion[1,2]

Follow-up intervals should be determined by the treating physician, based on the clinical indicators. Agree with your patient and their caregiver(s) on the proposed follow-up timetable:

WEEKS 1–4	WEEKS 4–12	WEEKS 12–24
Weeks 1, 2, 3, and 4 Follow-up consultations	**Weeks 8 and 12** Follow-up consultations	**With PN/IV modification** Follow-up consultations every 4 weeks until stabilisation Standard laboratory tests every 4 weeks or more frequently if required **Without PN/IV modification** Follow-up consultations every 2–3 months

It is recommended that your patient and their caregiver(s) record weight, fluid intake, urine volume, urine specific gravity after PN/IV in the morning, and stool volume weekly, throughout their treatment as long as PN/IV is in a phase of reduction. Once the minimum level has been reached, decide how often to follow up with these clinical indicators.

A treatment duration of 6 months (excluding periods of ill health, such as catheter-related bloodstream infections or other intercurrent illnesses) is recommended, after which treatment effect should be evaluated. In children below the age of 2 years, treatment should be evaluated after 12 weeks. Continued treatment is recommended for patients who have been weaned from PN/IV.

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PN/IV, parenteral nutrition/intravenous fluids.

Assessments and laboratory monitoring

Clinical and nutritional assessments[1-3,7]

Suggested tests and assessments for follow-up consultations based on expert opinion

Every visit:

- PN/IV status
- Dietetic consultation to assess food intake (kcal or kJ) and nutrient content
- Body weight, body mass index
- General health, physical and mental state
- Signs of fluid overload
- Mid-upper arm circumference
- Signs of injection site reactions
- Concerns with stoma appearance or function (photograph of the stoma[s], if present)
- Any other new symptoms
- Concomitant medication(s)
  - Possible dose adjustment of oral medications that require titration or have a narrow therapeutic index

Monthly:

- Body length/height

Yearly:

- Body composition measurement

PN/IV, parenteral nutrition/intravenous fluids.

Fluid balance assessment[5]

Intake and output assessment (see patient diary data)

- 24-hour fluid intake
  - Type of drink (example: oral rehydration solution, mineral water, etc)
- 24-hour urine volume output
- Number of stools or ostomy outputs, stool consistency over time and compared with baseline

Review PN/IV requirements[1,5]

- See algorithm for PN/IV adjustment
- If PN/IV is reduced, plan a follow-up consultation the following month

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

PN/IV, parenteral nutrition/intravenous fluids.

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Suggested Revestive treatment follow-up checklist[1,2,8]

INVESTIGATION	Initiation	Weeks 2 and 4	Depending on PN/IV stability			6–12 months	Every year
			Q1W if PN/IV adjusted	Q4W if PN/IV adjusted	Q12–16W if PN/IV adjusted		
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, creatine, gluscose, 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	•						•
Faecal occult blood (mandatory)	•					•	
Colonoscopy (mandatory)*	•						•¶
Live ultrasound	•						•
Bone density scan	•						•

*Upper gastrointestinal endoscopy or other imaging is also recommended in addition to colonoscopy before and during treatment with Revestive; †Monitoring frequency is recommended as every one week or every four weeks, based on the patient's general condition and the clinician's discretion; ‡Includes sodium, chlorine, potassium, magnesium, calcium, and phosphorus; ¶Colonoscopy/signoidoscopy is recommended for all children and adolescents after 1 year of treatment, every 5 years therafter while on continuous treatment with Revestive, and if they have new or unexplained GI bleeding.

GI, gastrointestinal; PN/IV, parenteral nutrition/intravenous fluids.

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Maintenance of Revestive

You can prepare your patients for home injections with key information and resources with Takeda's homecare service.

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Educate your patients on the Revestive homecare service

Takeda provide a fully funded comprehensive homecare service, delivered by the homecare provider (Sciensus or HealthNet) and tailored to your department and patient needs*. This service includes a fully qualified homecare nurse meeting with you or your patient(s) in the hospital, providing training in your patient's home 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 provider (Sciensus or HealthNet) to patients with their monthly deliveries:

ANCILLARY ITEMS	QUANTITY/MONTH
Reconstitution needle (22 gauge)/ Green needle	28
Administration (s/c) needle (25G to 30G)	28
0.5ml/1ml leur lock syringes	28
Sharps bin (5L/ 11L/ 22L) or as requested	1
Alcohol swabs	56
Travel sharps bin (as required)	1 (when requested)
Wipes – small	100 every 8 weeks

*Ancillaries for Revestive, patient pathway and patient referral pathway may differ between homecare companies.

Patient pathway

YEAR 1	FULL PROGRAM
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 1; day 2-4)	6
Nurse visits (wk 2-3; twice per week)	4
Nurse visits (wk 4-5; once per week) Followed by hospital review	2
Nurse visits (wk 8)	1
Nurse visits (wk 12, 16, 20, 24, 28; Once per week)	5
Nurse visits (wk 35, 43, 51; Once per week)	3
Subtotal of nurse visits in Y1	**24**
Outgoing field nurse phone calls Y1 24 hours after nurse visit	**22**
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

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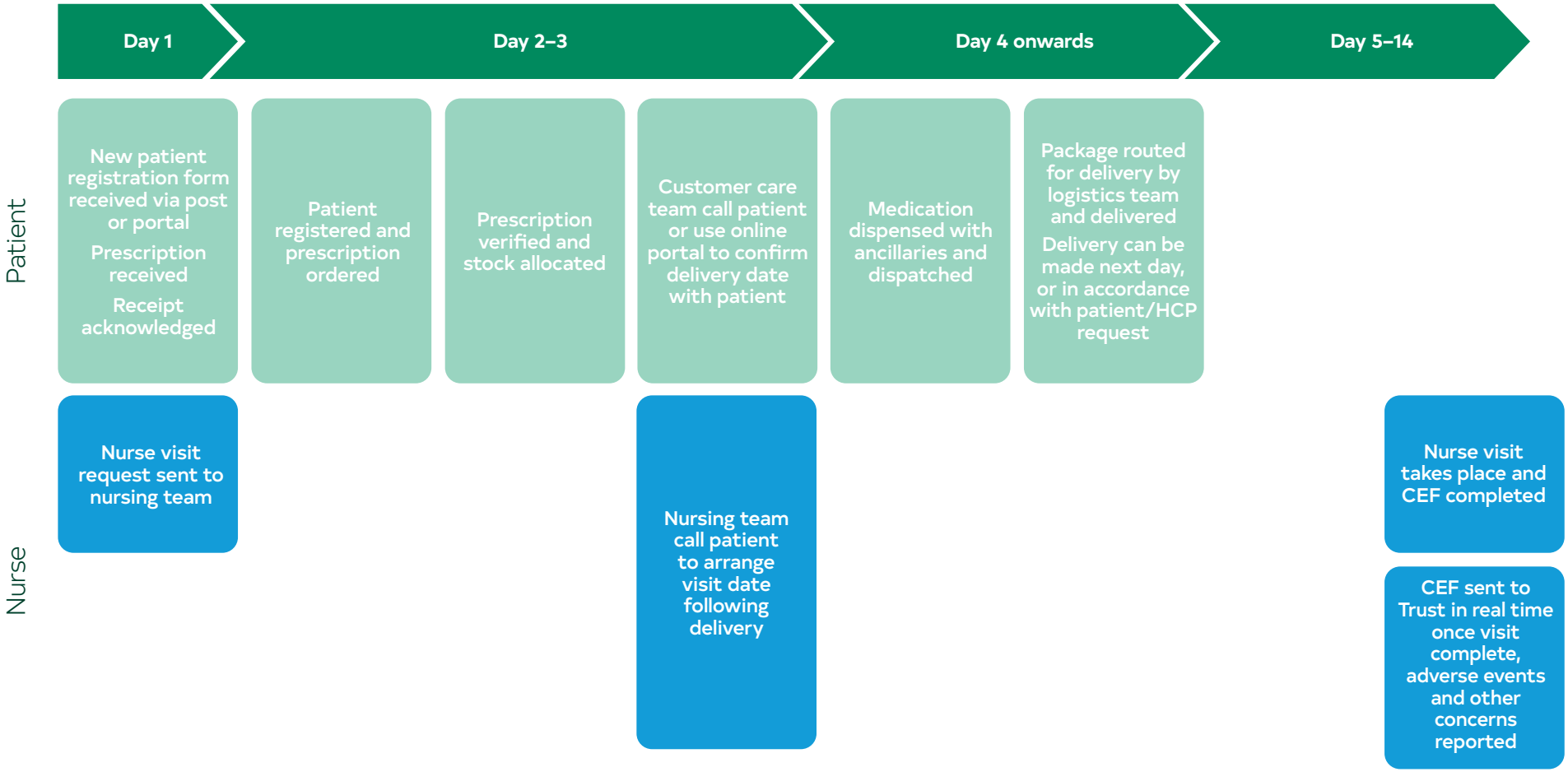
Homecare Patient Referral Pathway

The below is an example pathway, however, please contact your chosen homecare provider for further information on their individual service.



This time frame is based on an example, each homecare provider will discuss and share their referral pathway during service set-up.
CEF, clinical evaluation form; HCP, healthcare professional.

References: 1. Revestive (teduglutide) Summary of Product Characteristics; **2.** Seidner DL, et al. *JPEN J Parenter Enteral Nutr* 2013;37:201–211; **3.** Hill S, et al. *Clin Nutr* 2018;37:2401–2408; **4.** Kocoshis SA, et al. *JPEN J Parenter Enteral Nutr* 2020;44:621–631; **5.** Clinical Study Protocol TED-C14-006. Amendment 4, version 5.0. Available at: clinicaltrials.gov/ProvidedDocs/81/NCT02682381/Prot_003.pdf. Accessed February 2025; **6.** Jeppesen PB, et al. *Gastroeneterology* 2012;143:1473–1481; **7.** Puntis J, et al. *Clin Nutr* 2018;37:2392–2400 **8.** Pironi L, et al. *Clin Nutr* 2020;39:1645-1666.

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