Reimbursement Criteria for Adults in a Nutshell § 10670000

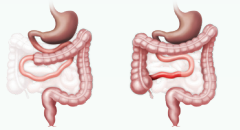
The teduglutide-based pharmaceutical specialty is eligible for reimbursement among eligible beneficiaries, for the treatment of **short-bowel syndrome** type 1 (SBS, terminal jejunostomy), type 2 (SBS, jejuno-colic anastomosis) or type 3 (SBS, jejuno-ileal anastomosis) **as a result of intestinal resection** and underlying **chronic intestinal insufficiency** characterized by reduction of intestinal function below the minimum required for adequate nutrient absorption and requiring **parenteral nutritional support** to maintain energy, protein, hydroelectrolyte and micro-nutrient balance and to maintain the health status and/or growth of the entitled.

Belgian reimbursement criteria

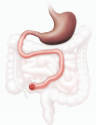
- Patient with minimum age of 1 year.
- The beneficiary is treated by a specialist doctor experienced in the treatment of SBS and associated with Belgian center that has signed **the convention for Extra-muros care in the context of parenteral nutrition for adults and/or children with the NIHDI (RIZIV/INAMI).**
- The beneficiary has **no active or suspected cancer and has no antecedents of cancer in the gastrointestinal system** including the hepatobiliary system during the last 5 years.
- Before initiating treatment, **a colonoscopy with exeresis of any polyps** must be performed on all beneficiaries.
- Reimbursement is authorized, based on an electronic application submitted by the prescribing physician-specialist identified and authenticated through **the eHealth platform**.

PN/IV stable phase

Parenteral support with fluid and nutrients has been optimized and stable since at least 3 months after the end of the minimal intestinal adaptation period. It is assumed that the beneficiary is in stable phase if he/she meets the following criteria:



Jejunocolic anastomosis = type 2 **Jejunoileal anastomosis = type 3**



End-jejunostomy = type 1

- Needed **at least 3 parenteral administrations/week** and **at least 3 liters/week** for at least 3 months.

AND

- Over the last 3 months, the **volume** of parenteral support has changed by **no more than 10%.**

AND

- The likelihood that parenteral support can be reduced and/or discontinued in the following 6 months is considered low by the treating physician based on the recipient's anatomical, physiological and medical profile.

AND

- In beneficiaries with a terminal jejunostomy, there is no chance of restoring continuity of the bowel

Start Revestive® treatment in the induction period

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section "Undesirable effects" for how to report adverse reactions.

C-APROM/BE/REV/0022 - July 2021. E.R. : Vincent Seynhaeve - Takeda Belgium NV, Leonardo Da Vincilaan 7, 1930 Zaventem.

Takeda

Revestive® teduglutide

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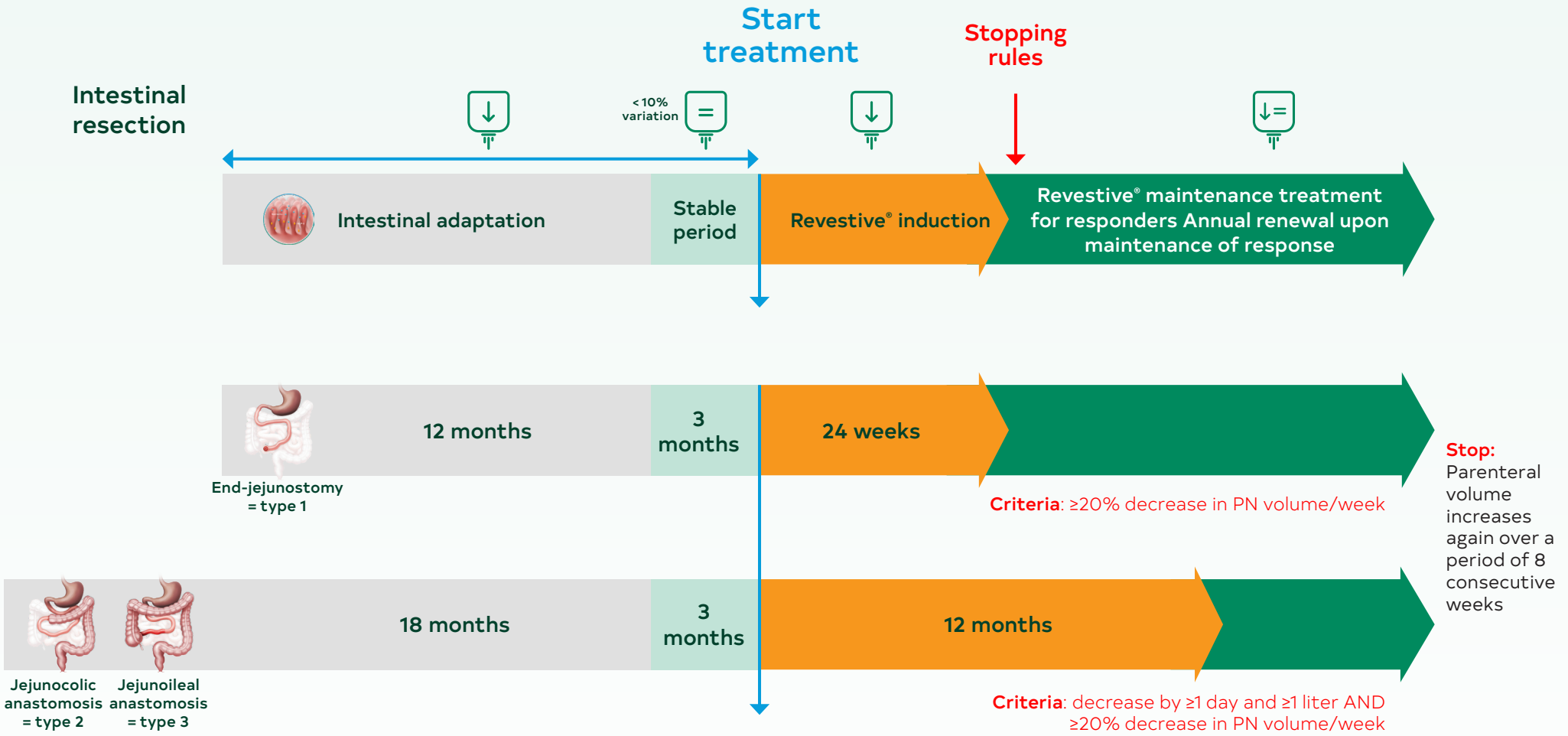

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Revestive® teduglutide