

Gattex[®] (teduglutide) – Expanded indication

- On May 16, 2019, **Takeda Pharmaceuticals announced** the FDA approval of **Gattex (teduglutide)**, for the treatment of adults and pediatric patients 1 year of age and older with Short Bowel Syndrome (SBS) who are dependent on parenteral support (PS).
 - Gattex was previously approved in adult patients only.
- In children, SBS is a life-threatening, chronic, and rare malabsorption disorder resulting from surgical removal of a large portion of the intestine, which is typically due to congenital or acquired conditions of the newborn or trauma. A goal of SBS treatment is to restore the remaining intestine's ability to absorb nutrients and reduce long-term dependence on PS.
- The approval of Gattex's expanded indication was based on a study in 59 pediatric patients aged 1 year through 17 years with SBS who were dependent on PS. Patients chose whether to receive Gattex or standard of care.
 - At the end of the 24-week study, 69% of patients (18/26) who took Gattex 0.05 mg/kg each day reduced PS volume by 20% or more. At week 24, 38% of patients were able to reduce PS infusion by at least 1 day per week.
- In an open-label, long-term extension study of pediatric patients who completed the study above, patients received additional treatment with Gattex if they deteriorated or stopped improving after discontinuation of prior Gattex treatment. Of the 15 patients who initially responded in the previous study and enrolled in the extension study, 13 patients (87%) required additional treatment with Gattex.
 - Efficacy results at the end of the first 24-week treatment period in the extension study were similar to those achieved at the end of 24 weeks treatment in the original study.
- The recommended dosage of Gattex in adult and pediatric patients is 0.05 mg/kg once daily administered by subcutaneous injection.
 - Gattex is for adult self-administration or caregiver administration. Self-administration in pediatric patients has not been tested.
 - Use of Gattex is not recommended in pediatric patients weighing less than 10 kg.
 - Refer to the Gattex drug label for additional dosing recommendations.