

## Lutathera® (lutetium Lu 177 dotatate) - Expanded indication

- On April 23, 2024, <u>Novartis announced</u> the FDA approval of <u>Lutathera (lutetium Lu 177 dotatate)</u>, for the treatment of adult and pediatric patients 12 years and older with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors.
  - Lutathera was previously approved in adults only.
- The approval of Lutathera for the expanded indication was supported by evidence from an
  adequate and well-controlled study of Lutathera in adults with additional safety, pharmacokinetic,
  and dosimetry data in pediatric patients aged 12 years and older with somatostatin receptorpositive tumors, including 4 pediatric patients with GEP-NETs.
  - The risks of radiation exposure associated with Lutathera are greater in pediatric patients than in adult patients due to longer life expectancy. Continued follow-up is recommended for evaluation of long-term effects.
- The recommended Lutathera dosage for adult and pediatric patients 12 years and older is 7.4
   GBq (200 mCi) via intravenous infusion every 8 weeks (± 1 week) for a total of 4 doses.



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