**Non-oncology Competitors**

Multiple new subcutaneous drugs and formulations are expected to be available or are already approved in 2025, offering potential benefits like increased convenience, improved treatment adherence, and reduced healthcare burdens.

Key developments in subcutaneous medications

* Alzheimer's Disease: Subcutaneous Leqembi (lecanemab) is awaiting FDA approval for at-home, once-weekly administration for early Alzheimer's disease, with a decision expected by August 31, 2025. This would provide a more convenient option compared to current intravenous infusions.
* Cancer:
  + Subcutaneous Keytruda (pembrolizumab) is under FDA review for various cancers and could be approved by September 23, 2025. This would offer a faster and more convenient treatment option for patients currently receiving intravenous infusions.
  + Sarclisa (isatuximab): Data supports the use of subcutaneous administration via an on-body injector, potentially shortening treatment times for multiple myeloma.
* Diabetes: Kirsty (insulin aspart-xjhz), the first interchangeable biosimilar to Novolog (insulin aspart), has been approved by the FDA for improving glycemic control in adults and pediatric patients with diabetes. Merilog (insulin aspart-szjj) was also approved in February 2025 as a biosimilar to Novolog, [according to Lexology](https://www.google.com/url?sa=i&source=web&rct=j&url=https://www.lexology.com/library/detail.aspx?g%3D536daed6-c183-45b4-9e72-03c8b421db6d&ved=2ahUKEwjDoez57dCOAxX2j4kEHVUnHnAQy_kOegQIABAK&opi=89978449&cd&psig=AOvVaw06u8HENK4L0EHk44Tn2mML&ust=1753287205482000).
* Hereditary Angioedema (HAE): Donidalorsen, a subcutaneous injection, is pending FDA approval for preventing HAE attacks, with a decision expected by August 21, 2025. It is a first-in-class RNA-targeted therapy that works by lowering a protein called prekallikrein involved in triggering HAE attacks. Sebetralstat, another HAE treatment, received FDA approval on July 3, 2025, to treat acute attacks of hereditary angioedema.
* Crohn's Disease: TREMFYA® (guselkumab), an IL-23 inhibitor, was approved by the FDA in March 2025, offering both subcutaneous and intravenous induction options for adults with moderately to severely active Crohn's disease. [Mount Sinai reports](https://www.google.com/url?sa=i&source=web&rct=j&url=https://www.mountsinai.org/about/newsroom/2025/guselkumab-demonstrates-superior-efficacy-in-landmark-clinical-trials-and-offers-new-hope-to-crohns-disease-patients&ved=2ahUKEwjDoez57dCOAxX2j4kEHVUnHnAQy_kOegQIABAN&opi=89978449&cd&psig=AOvVaw06u8HENK4L0EHk44Tn2mML&ust=1753287205482000) that guselkumab showed superior efficacy compared to ustekinumab in clinical trials.
* Other Approvals and Developments:
  + A ready-to-use subcutaneous bortezomib formulation was approved by the FDA and is anticipated to launch in the second quarter of 2025.
  + Belimumab (Benlysta) autoinjector was approved for children with lupus nephritis in June 2025, providing the first at-home, subcutaneous biologic option for this condition.
  + FDA approved a new presentation of ustekinumab-stba (Steqeyma) biosimilar in a single-dose vial for subcutaneous injection in June 2025, for plaque psoriasis and psoriatic arthritis in patients aged 6 to 17.
  + Supernus's SPN-830, a subcutaneous apomorphine infusion device, was approved for advanced Parkinson's disease, reducing OFF time by 1.89 hours daily.
  + Medtronic's Adaptive deep brain stimulation (aDBS) and BrainSense Electrode Identifier (EI) received FDA approval in February 2025, advancing personalized care for Parkinson's disease patients.
  + Elrexfio™ (elranatamab-bcmm), a subcutaneous bispecific antibody for relapsed or refractory multiple myeloma, received approval for a new dosing regimen in July 2025, allowing for once-monthly therapy in certain patients.

These new subcutaneous drugs and formulations represent a growing trend towards more convenient and potentially more effective treatment options for patients with a range of conditions.