

October 2023

Important Update about Ophthalmic Drug (Avastin) for Medicare Advantage Providers

Florida Blue is aware of a voluntary product recall initiated by Pine Pharmaceuticals that could impact the supply of bevacizumab (Avastin[®]) compounded for ophthalmic use.

Summary of Voluntary Recall

Pine Pharmaceuticals is one of three companies that produces compounded bevacizumab for ophthalmic use. On October 2, Pine Pharmaceuticals initiated a voluntary product recall due to an observation by the U.S. Food and Drug Administration (FDA). The observation cited concerns of possible serious infections related to a potential lack of sterility assurance for repackaged Avastin intended to be sterile, when produced with specific equipment.

Drug Alternatives

Compounded bevacizumab is a preferred product included on the list of Step Therapy medications defined by Florida Blue. The list also includes non-preferred alternatives for ophthalmic use. The Centers for Medicare & Medicaid Services (CMS) has authorized Medicare Advantage plans to use Step Therapy for Part B drugs as part of a patient-centered care coordination program. Step Therapy is required, and the definition of medical necessity must be met, for certain higher-cost non-preferred medications.

There are two other 503B compounding facilities that are approved to prepare ophthalmic bevacizumab – the preferred product. These facilities are Fagron Sterile Services, LLC and RC Outsourcing, LLC. Providers have the option to obtain bevacizumab from these other suppliers. If you are unable to acquire the medication from an alternate source, you can request another alternative from the list of Step Therapy non-preferred drugs (pre-authorization applies).

Note: Step Therapy may only be applied to new prescriptions or administrations of Part B drugs for members who are not actively receiving the affected medication.

More information about [Step Therapy and the current list of medications](#) are available at [FloridaBlue.com/providers](https://floridablue.com/providers).

To learn more about the compounded product recall, please visit the FDA website at [fda.gov](https://www.fda.gov).