

Manufacturer Data - New Specialty Drug Filings for 2022

Background:

Under ORS 646A.689, Manufacturers are required to report new prescription specialty drugs for sale in the United States within 30 days of introduction. Specialty drugs are defined as "a drug for sale in the United States at a price that exceeds the threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program".

Data sources utilized:

Data reported by the manufacturer to the Oregon Drug Price Transparency (DPT) program in iReg. Items marked as trade secret (TS) in this report were flagged by the manufacturer as trade secret in iReg and have been redacted from this report.

Package quantity and size information was pulled from Medi-span. If no match on the NDC was found, these fields were left blank for the drug. Therapeutic equivalent and biosimilar information pulled from Orange Book TEE codes and Purple book reference product information. Approval dates pulled from the FDA's Orange and Purple books respectively.

Data timeframe:

New specialty drugs filed from 1/1/2022 to 12/31/2022

Definitions:	
Drug price:	The package cost for the NDC as reported by the manufacturer in iReg.
FDA priority:	Whether the United States Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review.
Patients per month:	The manufacturer's estimate of the average number of patients who will be prescribed the new prescription drug each month.
Price per unit	Calculated by: Drug price / (Package Size x Package Quantity)
Drug approved through an expedited pathway	The prescription drug application qualified for one or more of the following expedited approval processes: fast track approval, priority review, accelerated approval, or breakthrough therapy designation.
Patent expiration date within 18 months	If "yes" is listed in this field, then the max patent expiration date listed for the drug application in the orange/purple book expires within the next 18 months. If "no" is listed in this field, then the max patent expiration date listed for the drug application in the orange/purple book does not expire within the next 18 months. If "no data" is listed in this field, then patent date information could not be located for the application associated with the drug.
Exclusivity expiration date within 18 months	(For non-biologics) If "yes" is listed in this field, then the max exclusivity expiration date listed for the drug application in the orange book expires within the next 18 months. If "no" is listed in this field, then the max exclusivity expiration date listed for the drug application in the orange book does not expire within the next 18 months. If "no data" is listed in this field, then exclusivity date information could not be located for the application associated with the drug. (For biologics) the exclusivity date used was based on 12 years from the date of the initial application approval. Drugs with a date set to expire in the next 18 months were marked as "yes", others were marked as "no".
Beginning 2022 package WAC	The Wholesale Acquisition Cost (WAC) for a package of the drug as of 1/1/2022.
End 2022 package WAC	The Wholesale Acquisition Cost (WAC) for a package of the drug as of 12/31/2022.
WAC price change % 2022	The price increase/decrease in package WAC from the beginning to the end of 2022.
Avg YoY price change (over past 5 years)	Average percent of the change in the year over year unit WAC for the last five years.

Manufacturers reporting: 151

NDCs reported: 367