

The 2019 Formulary Exclusion List Season Is Here – Get Smart for Yourself and Your Brand

Executive Summary

With Express Scripts' (ESI) recent publication of its "2019 Formulary Exclusion List Changes," and CVS Health's version expected around October 1, 2018, the implications of this management tool are now beginning to be known. These lists, which include specific drugs that will no longer be covered on the pharmacy benefits managers' National Preferred Formulary – have increased in number [by nearly 160%](#) since 2014. In 2017, exclusions caused approximately 300,000 patients to "switch their medication."

Formulary exclusions have implications beyond just the lost revenues resulting from medication switches. Brands that are better positioned compared with their competitors often use the lists as powerful marketing and messaging tools to shape HCP and patient impressions about their broader formulary coverage footprint.

This POV discusses the ESI and CVS lists, provides tips to help you understand the relevant facts, and includes scenarios to consider in light of the upcoming changes.

Key Features

Express Scripts listed 48 new formulary exclusions, including Gilead's HIV treatment Atripla, Abbvie's hepatitis C treatment Mavyret, and Sanofi's hemophilia treatment Eloctate. See the full list [here](#).



Further exclusions include 22 drugs that have low-cost generic alternatives; 12 instances of brand-to-brand competition where the drugs have the same active ingredient, but the excluded drug has a higher net cost; 11 specialty drugs that have a lower-cost brand or biosimilar alternative with a lower list price; 10 drugs that are multisource brands with direct generic equivalents; nine short-term therapies, such as topical creams and ophthalmic treatments.

CVS Health will be removing 23 drugs from its standard formulary while adding four. Details are not available yet, but the full list of 2019 changes is expected to be available around October 1.



Implications for Pharma

HOW REAL IS REAL?

- 01.** Without a doubt, many brands will lose some revenue as a result of these exclusions. However, the true impact will need to be assessed on a brand-by-brand basis due to a variety of factors (described in more detail below).
- 02.** Brand teams whose products are added to these lists will be concerned, and some – but not all – of that concern will be warranted.

03. The media will make a big deal about these lists, so expect to see many mentions in trade publications and e-newsletters.

GET SMART: QUESTIONS AND CONSIDERATIONS

01. What is your brand's payer mix? Formulary exclusion lists have an outsized impact on commercial coverage and less impact on Medicare, Medicaid or veterans affairs. So in order to determine how big the impact will really be, it's important to determine how many patients are actually likely to be impacted.

Sample case: Certain hepatitis C products were excluded by ESI while others were not. While this is a fact, the reality is that most new prescriptions to treat hep C are written for Medicaid and Medicare patients, not commercial patients. So the biggest impact is likely to come from a messaging and positioning standpoint, not actual brand sales.



02. How do these lists impact your brand and its competitors? When reviewing the ESI list, note that it is organized by "drug class." In some cases, only one brand within a class is now excluded, while in other cases, multiple brands are now excluded. It will be important to understand how many brands are actually affected to determine how strong an impact the list may have in steering market share.

Sample case: The growth hormone category has seven products that are now excluded, while the HIV category has only one. It is likely that the HIV brand will be significantly more affected than any individual growth hormone product.

03. The final verdict will not be known until the CVS list is released in October. While the ESI list will certainly affect many patients and cause a flurry of activity among pharmaceutical companies and in the media, it is prudent to wait to see what the landscape looks like once the CVS list is released.

Sample case: Here are the scenarios to look for once the CVS list is released:

- **Scenario 1:** Your brand is excluded on **both** CVS and ESI; this is the worst-case scenario, and will likely result in maximum damage to sales.
- **Scenario 2:** Your brand is excluded on **either** CVS or ESI; the true impact will be related more to messaging than actual sales, as the lists will likely cancel one another out.
- **Scenario 3:** Your brand is **not excluded** on either list but competitor(s) are; this is the best-case scenario for your brand. Plan to allocate marketing resources and activate brand teams to proactively message these details to HCPs and patients.

04. Will rare disease drugs be included on the CVS list? We don't know yet, but there is certainly a chance one or more will be. Preparing for that possibility now will save headaches later.

Conclusion

Formulary exclusion lists are here to stay and definitely have the ability to steer share from one brand to another. However, not all brands or patients will be affected. The devil is in the details, and the true implications will not be known until the CVS list is released in October.

If you're concerned about how your brand might be affected by the ESI and CVS exclusion lists, don't wait — reach out to your account team today.

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Want to learn more about Formulary Exclusion Lists?

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