<table>
<thead>
<tr>
<th>TABLE OF CONTENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Executive Summary</td>
</tr>
<tr>
<td>Background</td>
</tr>
<tr>
<td>Methodology</td>
</tr>
<tr>
<td>Results</td>
</tr>
<tr>
<td>Discussion</td>
</tr>
<tr>
<td>Appendix</td>
</tr>
</tbody>
</table>

GlaxoSmithKline provided funding for this analysis. Avalere maintained full editorial control, including selection of the vaccines, methodology, and content of the paper.
EXECUTIVE SUMMARY

While children’s vaccinations receive significant public attention, the prevalence of vaccine-preventable diseases is actually greater among adults than among children and is particularly high among seniors.\(^1\) While they vary by disease, vaccination rates among people over 65 years old remain low, despite most people in this age cohort having insurance.\(^2\) Many factors contribute to low adult vaccination rates, including limited public awareness about adult vaccinations, lack of vaccination requirements for adults, gaps in recommending vaccines for adults during health care visits, and complex insurance coverage for adult vaccines, among others.\(^3\) Given the persistence of mortality from vaccine-preventable illnesses in this country, Healthy People 2020 has a goal to increase immunization rates and reduce cases of these diseases. The Centers for Disease Control and Prevention also issues specific vaccination recommendations on 17 disease areas.

The Affordable Care Act (ACA)\(^4\) took a significant step toward eliminating coverage barriers to vaccination in the United States by requiring non-grandfathered group and individual market health plans to cover recommended\(^5\) vaccines at zero cost to enrollees. However, this provision of the ACA did not extend to Medicare Part D plans, resulting in Medicare beneficiaries being subject to, at times, substantial cost-sharing for these preventative services. Beginning in 2012, the Centers for Medicare & Medicaid Services (CMS) allowed Part D plans to create a Vaccine Tier to promote broader access, and in 2015 CMS encouraged Part D plans to consider offering $0 or low cost sharing for vaccines.\(^6\)

Avalere examined coverage trends for certain vaccines between 2011 and 2016, to determine if the requirements of the ACA or the encouragement from CMS had any effect on coverage in Medicare. We selected 10 vaccines from the list of recommended vaccinations maintained by the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices (ACIP), and focused on vaccines that either had age-specific recommendations for seniors or dealt with conditions for which seniors were a target population given their increased risks.

---

2. According to the CDC vaccination rates in 2014 among adults aged ≥65 years ranged heavily depending on the underlying condition. They were: 71.5% for the influenza vaccination, 61.3% for pneumococcal vaccination, 57.7% for tetanus, 27.9% for herpes zoster vaccination, 15.7% and 5.5% (among adults aged ≥50 years) for Hepatitis B and A respectively. \(^{Id.}\)
3. Id.\(^{Id.}\)
5. Recommended by the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices.
We found that approximately 12 percent of enrollees in Medicare Advantage Prescription Drug (MA-PD) plans had access to these vaccines in 2015 at zero cost sharing, up from less than 5 percent in 2011. No standalone Part D plans covered any of these vaccines with zero cost sharing during the entire 6 years included in our analysis. On average, MA-PDs are more likely to charge a fixed dollar copay—between $42 and $54 per vaccine on average. Meanwhile, standalone PDPs are split between copays and coinsurance—with average consumer out-of-pocket costs ranging between $14 and $102.

The cost sharing requirements for Medicare Part D enrollees to receive ACIP-recommended vaccinations are thus much higher than costs charged under most other insurance, where the ACA $0 cost-sharing rules apply. Given stated public health goals to increase vaccination rates, stakeholders may want to evaluate whether policy changes are needed to promote improved Medicare coverage to ensure adequate access to appropriate vaccinations for all Medicare enrollees.

BACKGROUND

In the context of persistently low rates of adult vaccinations and ongoing prevalence of vaccine-preventable diseases, federal policymakers have taken numerous steps to expand vaccination rates. Healthy People 2020 has a goal to increase immunization rates and reduce cases of these diseases. The Centers for Disease Control and Prevention issues recommendations on 17 vaccine-preventable conditions to help guide healthcare providers. The Affordable Care Act (ACA) also built on the CDC recommendations by requiring most health plans in the commercial market to cover vaccinations at no cost to the patient. Lastly, Medicare has encouraged Part D plans to adopt Vaccine Tiers with low cost-sharing to promote broader access to vaccines for the 39 million Medicare beneficiaries enrolled in Part D plans.

The CDC’s Advisory Committee on Immunization Practices (ACIP) publishes the General Recommendations on Immunization and released its most recent update in January 2011. The ACIP general recommendations provide overall guidance and vaccine-specific recommendations on 17 vaccine-preventable diseases, which are intended to help providers assess the benefits and risks of these vaccines. These guidelines are based on an expert panel review, and are scheduled to be updated every three to five years. ACIP recommendations are subject to review by the Director of the CDC and are almost always adopted.

The passage of the Affordable Care Act (ACA) in 2010 aimed to increase vaccination rates in the United States. Section 2713 of the ACA set coverage mandates regarding preventive services that included a requirement that all non-

Adult Vaccination Coverage in Medicare Part D Plans

grandfathered group and individual market health plans must offer ACIP-recommended vaccines with zero cost-sharing. However, this requirement does not extend to the Medicare Part D program, creating confusion for some beneficiaries seeking recommended vaccinations.9

In 2015, CMS addressed immunizations and vaccinations rates in its annual Call Letter to Part D plans. In the Call Letter, CMS noted that adult immunization rates remain low despite ACIP recommendations and the Healthy People 2020 goal of increasing immunization rates and reducing preventable infectious diseases. In an effort to increase immunization, especially among the elderly population, CMS encouraged Part D plans to cover vaccines at $0 or low cost sharing “to promote this important benefit”.10

Part D plans, including standalone Prescription Drug Plans (PDPs) and Medicare Advantage plans with drug coverage (MA-PDs), assign all covered drugs to a specific formulary tier. Each tier then has either an associated copay, expressed as a fixed dollar amount, or coinsurance rate, expressed as a percentage of the cost of the drug. CMS allows Part D plans to have up to six tiers, although the 6th tier is only allowed if it provides a “meaningful benefit.” CMS provides that including “a $0 vaccine-only tier, a low or $0 cost-sharing tier for special needs plans (SNP) targeting one or more specific conditions (e.g., $0 tier for drugs related to diabetes and/or smoking cessation)” would be examples of meaningful benefits.11

Part D plans assign drugs and vaccines to formulary tiers for a variety of reasons, including to influence both enrollee and prescriber choice. In some cases, tier placement can encourage use of lower cost products by reducing the cost-sharing for the tier; many generic tiers have low or zero dollar cost sharing amounts in order to encourage enrollees to use these low-cost drugs instead of higher-priced brand drugs. Likewise, formulary design can encourage use of drugs that are expected to reduce other medical spending; for example, a health plan may wish to encourage utilization of vaccines in order to prevent the medical costs associated with contracting the actual disease. The Congressional Budget Office (CBO) has recognized that adherence to prescription drugs can reduce Medicare spending on medical services.12 Conversely, products placed on higher cost-sharing tiers can discourage utilization.13 Finally, because tier placement can drive product utilization, plans use tier placement as one of several factors to negotiate for price concessions (i.e., rebates) from manufacturers.

Notably, the incentives for tier placement can vary between MA-PD plans and standalone PDPs. MA-PD plans are responsible for both the medical and pharmacy spending of their enrollees, and may place drugs on tiers in order to encourage utilization of pharmacy products that could reduce medical spending. If successful, the MA-PD plan would have lower overall costs, as often the spending associated with medical services can be much higher than the spending associated with pharmacy costs. Standalone PDPs, however, do not have such explicit financial incentives, since these plans do not directly benefit from lower medical spending. Therefore, it is useful to examine the coverage trends separately for PDPs and MA-PD plans. In 2015, there were 23.9 million beneficiaries enrolled in standalone PDPs and 13.5 million beneficiaries in MA-PDs (excluding employer group waiver plans or EGWPs).

Importantly, in the Part D market, enrollees who are eligible for the low income subsidy (LIS) are not subject to cost sharing that varies based on the tier placement of the drug. In 2016, there are approximately 36 percent of Medicare beneficiaries enrolled in Part D are eligible for the LIS. For the non-LIS beneficiaries with Part D coverage, these individuals must pay the cost sharing dictated by the Part D benefit design for their plan.

While not required, many Part D plans apply a deductible; in 2016 the maximum drug deductible allowed by CMS is $360. Once this deductible has been reached, beneficiaries will pay only the cost sharing associated with the specific drug until total Part D spending reaches $3,310. At this point, the average enrollee shifts into the “donut hole”, during which they pay either 45 percent of the cost of brand drugs or 58 percent of the cost of generic drugs. Enrollees who reach $4,850 in total out-of-pocket costs during the year enter the catastrophic phase of Part D, at which point they pay the greater of 5 percent of the cost of each drug or $2.95 for generic drugs and $7.40 for brand drugs. Of note, some Part D plans modify this benefit structure based on a variety of factors.

Vaccine coverage under Part D is further complicated in that most vaccinations must be administered by a provider. In some cases, patients may be required to pay the full amount of the vaccine to their physician and then submit a claim to their Part D plan for reimbursement. CMS has been encouraging plans to improve vaccine access without requiring upfront payment by the patient. In addition, as noted above, since 2012 CMS has allowed Part D plans to use the 6th tier as a $0 vaccine-only tier.

15 2015 Medicare Trustees Report.
METHODOLOGY

For purposes of this analysis, Avalere selected 10 vaccines that cover seven different conditions from the ACIP list of recommendations. We chose vaccines that either had specific over-age 65 recommendations or dealt with diseases for which seniors were a target population given their increased risks for the underlying condition.

Table 1. Products Included in Analysis and Selection Criteria

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Selection Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boostrix (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed)</td>
<td>Age</td>
</tr>
<tr>
<td>Zostavax (Zoster Vaccine Live)</td>
<td>Age</td>
</tr>
<tr>
<td>Varivax (Varicella Virus Vaccine Live)</td>
<td>Age</td>
</tr>
<tr>
<td>Menomune (Meningococcal Polysaccharide Vaccine, Groups A, C, Y, W135 Combined)</td>
<td>Age/Condition</td>
</tr>
<tr>
<td>Havrix (Hepatitis A Vaccine)</td>
<td>Age/Condition</td>
</tr>
<tr>
<td>VAQTA (Hepatitis A Vaccine, Inactivated)</td>
<td>Age/Condition</td>
</tr>
<tr>
<td>Energix-B [Hepatitis B Vaccine (Recombinant)]</td>
<td>Age/Condition</td>
</tr>
<tr>
<td>RECOMBIVAX-HB [Hepatitis B Vaccine (Recombinant)]</td>
<td>Age/Condition</td>
</tr>
<tr>
<td>Twinrix [Hepatitis A Inactivated &amp; Hepatitis B (Recombinant) Vaccine]</td>
<td>Age/Condition</td>
</tr>
<tr>
<td>Tenivac (Tetanus and Diphtheria Toxoids, Adsorbed)</td>
<td>Age</td>
</tr>
</tbody>
</table>

Part D formulary status is specific to the National Drug Code (NDC) for each drug or vaccine. A single drug or vaccine may have multiple NDCs that reflect differing dosages, strengths, route of administration, or other factors. We identified all of the NDCs for each of the 10 vaccines in our analysis from the list maintained by the Food and Drug Administration.

We next used the Avalere DataFrame® to identify the tier placement for each of the NDCs in our analysis from 2011 through 2016. DataFrame® is a proprietary database maintained by Avalere Health that aggregates Part D formulary information and detailed drug data. We identified the specific tier placement for each plan in each year, including instances where plans did not cover the vaccine. Finally, we determined the total Part D enrollment for each plan as of July of each year. For the 2016 evaluation, we used July 2015 enrollment data.

17 Boostrix was first approved for individuals over 65 in mid-2011.
18 Tenivac was approved in mid-2013 and first appears in this analysis in 2015.
19 National Drug Code Directory, available online here: [link](#).
20 For more information concerning the Avalere DataFrame® product, see here: [link](#).
Due to data limitations, we could not determine actual Medicare Part D utilization of these vaccines. A number of the vaccines are recommended by ACIP only if the person has never been previously vaccinated; for example, the current recommendation for Tdap states “ACIP recommends that all adults aged 19 years and older who have not yet received a dose of Tdap should receive a single dose … Currently, Tdap is recommended only for a single dose across all age groups.” As such, demand for some of these vaccines in Medicare may be limited.

RESULTS

Few Part D Plans Use a Vaccine Tier

In its first year as an option, 2012, only 44 MA-PD plans (2.1 percent of total plan offerings in 2012) which combined covered approximately 640,000 enrollees (6.1 percent of 2012 MA-PD enrollment) included any of the 10 drugs in our analysis on a Vaccine Tier. By 2015, 66-72 MA-PD plans (2.9-3.2 percent of MA-PD plans offered in 2015) with a combined approximately 880,000-950,000 enrollees (6.5-7.0 percent of MA-PD enrollees in 2015) were using the Vaccine Tier for these products. Notably, no standalone PDP plans have ever used the Vaccine Tier for these products.

When covered, the 10 vaccines that were part of this analysis were most predominately covered on the preferred brand drug tier (see Appendix for detailed results). Zostavax was the only drug which remained most often covered at the non-preferred brand drug level in PDP plans and only became predominately covered at the preferred brand drug level in MA-PD plans after 2014.

---

21 Centers for Disease Control and Prevention. "Updated Recommendations for Use of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis (Tdap) Vaccine in Adults Aged 65 Years and Older — Advisory Committee on Immunization Practices (ACIP), 2012". Morbidity and Mortality Weekly Report, June 2012. Available here: link. CDC also notes "ACIP will begin discussions on the need for additional doses of Tdap and timing of revaccination of persons who have received Tdap previously".
Zero Dollar Cost Sharing for Select Vaccines Has Increased in MA-PDs but Remains Rare

Prior to 2012, between 6 and 21 MA-PD plans (0.3-1.0 percent of total plan offerings in 2011) with a combined 210,000-400,000 enrollees (2.3-4.2 percent of 2011 MA-PD enrollment) covered the ten vaccines in our analysis with no cost sharing. However, by 2015 approximately 210 MA-PD plans (9.2 percent of MA-PD offerings in 2015) with over 1.6 million enrollees (12.3 percent of MA-PD enrollees in 2015) provided these vaccines at no cost to their enrollees. Again of note, no standalone Part D plans have ever covered these ACIP-recommended vaccines on a zero dollar tier. Thus, while $0 coverage of vaccines has increased, the vast majority of Medicare beneficiaries must still pay cost-sharing for these immunizations.
MA-PD Plans Tend to Use Copays While Standalone PDPs Use Coinsurance

In 2015, there was a noticeable difference between the types of cost sharing that MA-PD plans used for the select vaccines compared to standalone PDPs. Approximately 80-90 percent of enrollees in MA-PD plans had a fixed-dollar copay for these vaccines, whereas between 47 and 72 percent of enrollees in standalone PDPs were in plans that used a fixed dollar copay, depending on the product.
Copay and coinsurance are comparable between MA-PD plans and PDPs, but coinsurance is higher in PDPs.

Copays for the select vaccines ranged between $42 and $54 in MA-PD plans and between $35 and $70 in standalone PDPs in 2015. For standalone PDPs, the average copay in 2015 was around $37 for most of the vaccines examined—with Zostavax averaging $57 and Tenivac averaging $35.

When coinsurance was used, average rates for the select vaccines ranged from 16 percent to 27 percent, depending on the product in MA-PD plans. Average coinsurance was higher in standalone PDPs, ranging from 28 percent to 39 percent by product. Based on the most recent prices for these vaccines, the enrollee actual out-of-pocket ranged from $10 to $72 in MA-PD plans and $14 to $103 in standalone PDPs. The variation in coinsurance rates was likely due to the wide range of tiers that Part D plans used for these vaccines.
Importantly, if an enrollee seeks these vaccinations at the beginning of the calendar year, they could be forced to pay for the full cost of the drug if covered on a tier subject to a drug deductible which can be as high as $360 in 2016. Conversely, if an enrollee who has already taken a significant number of Part D drugs during the year seeks a vaccination toward the end of the year, the costs could be reduced due to the catastrophic coverage provided by the Part D benefit structure. Thus, the timing of the administration can have a significant impact on the enrollee’s out-of-pocket costs.

Table 2. Enrollment Weighted Average Cost Sharing for Select Vaccines, 2015

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Example Part D Price22</th>
<th>Average Copay</th>
<th>Average Coinsurance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MA-PD</td>
<td>PDP</td>
<td>MA-PD</td>
</tr>
<tr>
<td>Boostrix</td>
<td>$38.03</td>
<td>$52.48</td>
<td>$37.13</td>
</tr>
<tr>
<td>Zostavax</td>
<td>$188.14</td>
<td>$54.00</td>
<td>$57.54</td>
</tr>
<tr>
<td>Varivax</td>
<td>$215.24</td>
<td>$41.94</td>
<td>$37.84</td>
</tr>
<tr>
<td>Menomune</td>
<td>$123.55</td>
<td>$52.11</td>
<td>$37.46</td>
</tr>
<tr>
<td>Havrix</td>
<td>$127.69</td>
<td>$52.55</td>
<td>$37.12</td>
</tr>
<tr>
<td>VAQTA</td>
<td>$62.74</td>
<td>$52.72</td>
<td>$37.12</td>
</tr>
<tr>
<td>Energix-B</td>
<td>$157.50</td>
<td>$52.09</td>
<td>$37.44</td>
</tr>
<tr>
<td>RECOMBIVAX-HB</td>
<td>$183.55</td>
<td>$53.37</td>
<td>$37.18</td>
</tr>
<tr>
<td>Twinrix</td>
<td>$276.65</td>
<td>$52.60</td>
<td>$37.12</td>
</tr>
<tr>
<td>Tenivac</td>
<td>$260.12</td>
<td>$53.23</td>
<td>$35.26</td>
</tr>
</tbody>
</table>

Source: Avalere Health DataFrame®

22 Reflects the negotiated cost to the plan, which acts as the basis for beneficiary cost-sharing. These prices are examples based on a single Part D plan. Retrieved from Medicare.gov Planfinder on December 1, 2015. Represent prices for Part D plan SS820-016 in zip code 60657. Prices do not include separate vaccination administration fee of $20.
DISCUSSION

Despite broad efforts by policymakers to expand rates of adult vaccinations, Medicare Part D plans continue to apply cost-sharing for these vaccines that may limit access for beneficiaries. Healthy People 2020 set a series of goals related to immunization, including a broad goal to “reduce, eliminate, or maintain elimination of cases of vaccine-preventable diseases,” as well as specific goals to increase the portion of adults who are vaccinated against zoster and hepatitis B. The ACA further mandated that non-grandfathered health plans cover ACIP-recommended vaccines without any cost sharing for enrollees. Nonetheless, this free coverage of vaccines has not extended to Medicare Part D, where the majority of non-LIS Medicare enrollees in the Part D space must pay to receive these vaccinations, sometimes upwards of $100.

Within Part D plans, coverage of vaccines differs between MA-PDs and PDPs. MA-PDs, which are financially responsible for beneficiaries’ medical and pharmacy costs, are more likely to cover the selected vaccines with $0 cost-sharing. Further, those MA-PDs that do charge cost-sharing use fixed dollar copayments, rather than coinsurance, more often than standalone PDPs. This difference illuminates how plans that bear responsibility for all parts of the Medicare benefit may adopt a more comprehensive approach to avoiding immune-preventable illnesses. Because PDPs do not have the same financial incentives, policymakers may want to consider other requirements if they want to improve access to vaccines among PDPs. Such requirements could increase Medicare Part D premiums, though the magnitude of such an impact is likely modest.

Across the board, this study reveals that Part D access to vaccines is now more limited than it is for most commercial plans subject to the ACA. As such, if policymakers seek to improve adherence to ACIP recommendations and achieve the Health People 2020 goals, it may need to reevaluate existing Part D policies to further reduce barriers to vaccinations for seniors.

APPENDIX

Figure 4. Average Tier Placement for Select Vaccines by Enrollment, MA-PD and PDPs, 2011-2016
Adult Vaccination Coverage in Medicare Part D Plans
About Us

Avalere is a vibrant community of innovative thinkers dedicated to solving the challenges of the healthcare system. We deliver a comprehensive perspective, compelling substance, and creative solutions to help you make better business decisions. As an Inovalon company, we prize insights and strategies driven by robust data to achieve meaningful results. For more information, please contact info@avalere.com. You can also visit us at avalere.com.

Contact Us

Avalere Health
An Inovalon Company
1350 Connecticut Ave, NW
Washington, DC 20036
202.207.1300 | Fax 202.467.4455
avalere.com