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Biosimilar coding and reimbursement under Medicare Part B

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I. EXECUTIVE SUMMARY

In this study, we examine Medicare's current reimbursement policy for biosimilars. In particular, we mean biosimilar products not approved as "interchangeable" with the reference biologic product. At present, this refers to all biosimilar products approved by the Food and Drug Administration (FDA).[1] Medicare's current policy groups all biosimilars under the same HCPCS code and reimburses them all at the same rate based on a weighted average of their Average Sales Prices (ASPs). However, by statute, the reference biologic retains its separate Healthcare Common Procedure Coding System (HCPCS) code and is reimbursed based on a separate ASP. We recommend the elimination of shared ASP reimbursement and that biosimilar products be put on equal economic footing with both each other and the reference biologic by giving them separate HCPCS codes and ASPs. This conclusion is based on the following observations:

- Maintaining separate HCPCS coding and reimbursement for the reference biologic while forcing biosimilars to share a common HCPCS code and identical Part B reimbursement arbitrarily distinguishes these products and causes market distortions.
- These market distortions will negatively impact biosimilar adoption by physicians, and inhibit long-run investment in biosimilars and reduce entry of new products, which means fewer benefits from competition, such as lower prices, greater product choice, and better patient outcomes.
- Despite the current policy's intentions, maintaining shared ASP reimbursement for biosimilars will result in higher prices and higher spending on biologic drugs in the long run.

We briefly examine the impact of shared biosimilar HCPCS codes and ASP reimbursement on four important stakeholder groups, and find the following:

Patients:	Will face fewer product choices at higher costs, decreased access, and greater risk of disruption with shared HCPCS codes
Physicians:	Will have financial disincentive to use biosimilars, and thus have fewer products at higher prices available for patients under shared HCPCS codes
Payers:	Will be less able to leverage competition to drive better access and outcomes for patients under shared HCPCS codes
Manufacturers:	Will be less willing to invest in new products and enter given (1) the riskier pricing and demand environment and (2) arbitrary disadvantages they face, relative to the reference brand, under shared HCPCS codes

This study examines two existing Medicare Part B drug markets where competitive circumstances similar to those that exist for biosimilars have progressed under separate HCPCS codes and ASP reimbursement. In these markets, innovation, entry, and competition has occurred despite the higher entry barriers inherent for products applying for New Drug Applications (NDAs) or Biologics License Applications (BLAs). Our expectation is that greater levels of entry and competition will occur in biosimilars markets where entry costs are lower, so our examples are a conservative guide to the benefits of biosimilar competition under separate HCPCS codes.

1 This is because, given the current state of science, it is not currently feasible to fully characterize the large molecules involved in order to evaluate interchangeability.

We thank Ernst Berndt, Louis E. Seley Professor in Applied Economics at the MIT Sloan School of Management for helpful discussions.

II. THE SHARED HCPCS POLICY AND ITS INCENTIVES

II.A. Background

The Affordable Care Act established reimbursement for a given manufacturer's biosimilar as the ASP of that biosimilar plus 6% of ASP of the reference biologic.[2] In the CY 2016 Physician Fee Schedule final rule, issued in October 2015, the Centers for Medicare and Medicaid (CMS) determined that, starting January 1, 2016, Medicare Part B would classify all biosimilars for a given reference product under one billing and payment code. It would subsequently change its reimbursement for these products to 100% of the weighted ASP across the biosimilars plus 6% of the reference product's ASP.[3] In its July 2017 Proposed Rules, CMS requested comments regarding the Medicare Part B biosimilar payment policy, with a specific focus on economics of the biosimilar market place and the question of the economic impact of adopting individual reimbursement codes for each biosimilar product.[4]

II.B. Shared ASP inappropriately models biosimilar products after AB-rated generics

CMS explicitly modeled the blended biosimilar ASP reimbursement policy on its "multisource" ASP reimbursement policy for small molecule generic injectable drugs.[5] Under that policy, CMS groups AB-rated generic products together with their branded equivalents under the same billing and payment code and reimburses all at 106% the same blended ASP. An important context for this policy, however, is that AB-rated generic products are interchangeable at the pharmacy or hospital (without the need for physician consent unless the prescription is marked as "dispense as written"). In economic terms, these products are nearly "perfect substitutes," meaning that choices among alternatives are likely driven primarily by price. By setting reimbursement at a fixed level across highly substitutable products, the reimbursement authority theoretically gives buyers an incentive to seek a lowest priced alternative. However, this incentive effect is predicated on the interchangeability of the products, and breaks down absent that precondition. Moreover, using a shared ASP to achieve this objective has also been identified as a contributor to a number of unintended consequences–such as reduced entry and shortages.[6]

Biosimilar products do not fit the substitution model of AB-rated generic drugs because the FDA does not consider them to be interchangeable–either with each other, or with the reference biologic product. Key potential differentiating features include:

- Substitution for a product not deemed interchangeable by FDA requires consent from the treating physician, which is not generally the case for AB-rated generic drugs.

2 Centers for Medicare & Medicaid Services, HHS, 42 C.F.R. § 405, 410, 411, 414, 425, 495, available at https://www.gpo.gov/fdsys/pkg/FR-2015-11-16/pdf/2015-28005.pdf.

3 PhRMA, "Medicare Monday: Part B and biosimilars, part 2." accessed Oct. 5, 2017, http://catalyst.phrma.org/medicare-monday-part-b-and-biosmilars-part-2.
Centers for Medicare & Medicaid Services, "Part B Biosimilar Biological Product Payment and Required Modifiers," accessed Oct. 5, 2017, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-drugs/McrPartBDrugAvgSalesPrice/Part-B-Biosimilar-Biological-Product-Payment.html.
Law360, "10 Things to Know About U.S. Biosimilar Reimbursement," available at https://www.cov.com/-/media/files/corporate/publications/2016/04/10_things_to_know_about_us_biosimilar_reimbursement.pdf.

4 42 CFR Part 405, 410, 411 (Nov. 16, 2015), available at https://www.gpo.gov/fdsys/pkg/FR-2017-07-21/pdf/2017-14639.pdf.

5 In its November 2015 final rule, CMS states: "Because of the degree of similarity that biosimilars share with their reference products, we believe it is appropriate to price biosimilar products in groups in a manner similar to how we price multiple source or generic drugs. In other words, it is reasonable to look to our payment policy for multiple source drugs to guide our policy on payment for biosimilars because multiple source drugs are biosimilars' closest analogues compared to the other categories of drugs and biologicals for which we make payment under section 1847A of the Act, such as single source drugs." See Federal Register, Vol. 80, No. 220, Nov. 16, 2015, p.71097 available at https://www.federalregister.gov/documents/2015/11/16/2015-28005/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions.

6 See, e.g. Ali Yurukoglu, Eli Liebman, and David B. Riley, "The Role of Government Reimbursement in Drug Shortages," National Bureau of Economic Research, available at http://www.nber.org/papers/w17987.pdf,

- FDA labeling guidance for biosimilars recognizes the potential for different products to carry unique indications and usage instructions, while AB-rated generics carry identical label indications.[7]

The dynamics of competition among biosimilar products is therefore most analogous to competition in therapeutic classes among closely related, but non-interchangeable molecules; it is not comparable to competition among AB-rated generics.

CMS claims that it takes "no position on whether a biosimilar is completely or partially analogous to its biologic reference product as a clinical matter." However, in practice, its reimbursement policy treats biosimilars the same way it treats AB-rated generic drugs by lumping them under the same HCPCS code.[8] Meanwhile, it holds the reference biologic apart in a separate HCPCS code, precisely as if the biosimilars were not AB-rated for the reference biologic, which they are not.[9] Since there is little reason to expect differences between the reference biologic and its biosimilars to be either greater or less than differences among biosimilar products, this distinction in payment policy is arbitrary and creates market distortions.

II.C. Incentives

CMS' current biosimilar reimbursement policy affects biosimilar markets in two ways: (1) its direct effects on those who pay for these products–i.e., physicians and clinics, and (2) the knock-on effects of those incentives on manufacturers. In this instance, both are important, and point to significant concerns about the adoption of these products by physicians, and willingness of manufacturers to introduce new products and compete.

II.C.1. Grouping biosimilars creates a disincentive for providers to use them

The asymmetric treatment of the reference biologic and its biosimilars in the current reimbursement environment creates a significant deterrent for physicians to adopt the biosimilar–particularly if there is more than one biosimilar product on the market. The root cause of this is the uncertainty that a shared ASP introduces in the reimbursement that providers receive for biosimilar products. Once there is more than one competitor sharing the biosimilar HCPCS code, the ASP will be an average of the prices of products in the category, which disconnects reimbursement to the provider from the cost of the particular product purchased. Reimbursement becomes more variable, as well. For example, purchasers of one product could see their reimbursement fall because some other product lowered in price, even though the product they bought did not change in price. A drop in the shared ASP can even lead to a situation where the doctor is "upside down" and reimbursed less than they paid for the biosimilar they chose.[10] This means that providers buying a biosimilar take on a financial risk due to the variability of the ASP–a situation that is actually made worse by more competition among biosimilars.

A provider does not take on the same financial risk when purchasing the reference biologic. Because it has its own HCPCS code, the prices that go into the ASP calculation for the reference biologic are not cross contaminated by the prices of other products. This eliminates the risk that the price of some other product that a provider did not purchase (or may not have had access to) could control the amount received for the product they did purchase. This does not mean that

7 See U.S. Department of Health and Human Services Food and Drug Administration, "Labelling for Biosimilar Products – Guidance for Industry (draft guidance), Mar. 29, 2016, p. 11, available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM493439.pdf.

8 CMS Final Rule, p. 71097.

9 "Although lack of statutory authority prevents us from pricing a biosimilar reference product with biosimilar products, like multiple source drugs, we see biosimilars competing for market share with each other, as well as competing with the reference or innovator product." CMS Final Rule, p. 71097.

10 Although some providers may seem to get a windfall as a result of picking a biosimilar with a price lower than the ASP, this would largely be a matter of luck because the blended ASP is an average across prices paid by all providers for all products, and is updated with a 6-months' lag. Providers are very unlikely to be well-enough informed of these facts to predict how they might fare, or be able to mitigate their risks–particularly if they carry any inventory.

the ASP of the reference biologic will not go down in the face of therapeutic competition from biosimilars. It can. We demonstrate this with examples of non-substitutable, yet competing Part B products.

The provider thus faces a decision between buying the reference biologic product with a predictable margin, and buying a biosimilar with a risky margin. This distortion ironically steers physicians away from picking biosimilar products. Moreover, this steering paradoxically gets worse with greater biosimilar competition, because, as more biosimilar products enter the market, the blended ASP becomes less predictable.

II.C.2. The blended ASP reduces incentives to introduce competing biosimilars

Creating a reimbursement disincentive for doctors to use biosimilars will have an obvious dampening effect on the commercial potential of these products and hence investment in them. Investment in many of the biosimilars in the current pipeline was initiated before the CMS final rule went into place, and those products may well come onto the market given that those investments are now mostly sunk costs. However, current and future investment in competitive biosimilar products will likely be adversely affected.

The blended ASP creates a more subtle issue for competition as well, because it introduces pricing externalities. That is, one manufacturer's pricing decisions not only affect the reimbursement of its customers, but also directly affects the reimbursement of its competitors' customers through the shared ASP. This is not a typical competitive situation. At best, this greatly complicates the competitive dynamics among biosimilar products. The use of Wholesale Acquisition Cost (WAC) at product launch, and the 6-month lag in ASP reporting further complicate these dynamics, making it difficult to predict how pricing and reimbursement might evolve. These features inherently increase the riskiness of pricing and therefore profitability of biosimilar products, which will have a further dampening effect on investment in competitive biosimilar products.

The central problem with blending ASPs for biosimilars is the pricing externality that it creates. Both manufacturers and providers face riskier decisions as a result. This can lead to unpredictable and unintended consequences. Manufacturers may, for example, find it more profitable to pursue the more expensive and time-consuming path of obtaining a BLA for their biologics, rather than face the risks of biosimilars. This would slow introduction of new products and raise costs, and many products may simply not be pursued. As a result, the blended ASP could result in less competition, less product variety, less downward pressure on prices, and patients would have fewer solutions to the health care challenges they face.

Allowing biosimilar products to have their own billing and payment codes puts them on equal footing with the reference biologic, eradicates an externality, and creates better incentives for competition. In combination, these forces will likely stimulate the availability of a wider range of products at competitive prices leading to better patient access and utilization.

III. IMPACTS OF THE SHARED HCPCS POLICY

Figure 1 below illustrates the impact of biosimilar reimbursement under a shared HCPCS code compared with a reimbursement policy that provides a separate HCPCS code for each biosimilar. This analysis considers the impact of these policies on four important health care stakeholder groups: (1) patients, (2) physicians, (3) payers, and (4) manufacturers.

Figure 1: Stakeholder impacts of shared HCPCS code reimbursement for biosimilars

Stakeholder	Separate HCPCS code	Shared HCPCS code	Impact
Patients	• More biosimilar products available • Broader range of suitable products • Lower out of pocket costs • Better access and adherence • Less risk of therapy disruption	• Fewer biosimilar products available • Smaller range of suitable products • Higher out of pocket costs • Decreased access and adherence • More risk of therapy disruption	**Patients will face fewer product choices at higher costs, decreased access, and greater risk of disruption with shared HCPCS codes**
Physicians	• Less reimbursement risk and potential to be "upside-down" on drug costs relative to reference product • Broader range of suitable products for patients • Lower patient costs drives better access and adherence to prescribers' protocols • Less risk of supply disruption	• Financial disincentive to use biosimilar due to reimbursement risk and potential to be "upside-down" on drug costs relative to reference biologic • Fewer suitable products for patients • Higher patient costs with lower access and adherence • More risk of supply disruption	**Physicians will have financial disincentive to use biosimilars, and thus have fewer products at higher prices available for patients under shared HCPCS codes**
Payers	• Better able to leverage competition if there are more products available • Better able to offer patient affordable access to medication • Better patient access leads to better outcomes • Lower system costs	• Less able to leverage competition if there are fewer products available • Less able to offer patient affordable access to medication • Less patient access avoids better outcomes • Higher system costs	**Payers will be less able to leverage competition to drive better access and outcomes for patients under shared HCPCS codes**
Manufacturers	• Puts biosimilars on similar footing with reference biologic • Fewer distortions in pricing and demand environment • Buyers (physicians) placed at less financial risk when using biosimilars • More predictable investment environment • More incentive to invest in new products and enter the market	• Arbitrarily advantages reference biologic • Buyers (physicians) placed at financial risk when using biosimilars • Greater distortions in pricing and demand environment • Riskier investment environment • Less incentive to invest in new products and enter the market	**Manufacturers will be less willing to invest in new products and enter given the riskier pricing and demand environment and arbitrary disadvantages they face relative to the reference brand under shared HCPCS codes**

III.A. Patients

Patients will have fewer biosimilar product choices at higher costs, decreased access, and greater risk of disruption under a shared HCPCS system for biosimilar reimbursement. Eliminating shared HCPCS codes removes a distortion to competition, eliciting a broader range of products at better value. For patients this means more suitable options for treatment and greater access affordable medicine. Moreover, a robust biosimilar market reduces the risk of disruption to patient care, which has been a periodic affliction in the generic injectable market.

III.B. Physicians

Physicians face a significant disincentive to use biosimilars because of the greater reimbursement risks they face under the shared ASP system. The risk for physicians is that the shared biosimilar ASP can change in ways that have nothing to do with the price they paid for the biosimilar they chose to purchase. A drop in the shared ASP can even lead to a situation where the doctor is "upside down" and will be reimbursed less than he or she has paid for the biosimilar. This financial risk to the doctor does not exist for the reference biologic because it has its own HCPCS code. These distortions hamper competition, and create disincentives for biosimilar entry. Physicians will thus have a narrower range of treatment alternatives to offer patients under a shared HCPCS system for biosimilar reimbursement.

Eliminating the adverse incentives associated with the shared biosimilar HCPCS codes will aid their adoption by physicians, and removes a distortion to competition. For physicians this means a broader range of suitable options and better access to treatments for their patients. Increased utilization and adherence will likely lead to better patient outcomes, which matters to physicians. Moreover, a robust biosimilar market reduces the risk of disruption to patient care due to supply disruptions, which have been a periodic affliction in the generic injectable market.

III.C. Payers

Payers will have fewer biosimilar choices, and will be less able to leverage competition in markets affected by shared HCPCS codes. Eliminating shared HCPCS codes removes a distortion to competition, eliciting a broader range of products. Payers can leverage this competitive environment to achieve better value and provide more affordable access to their covered patients. Better patient access leads to better outcomes, which can lower system costs.

III.D. Manufacturers

Manufacturers of biosimilars are arbitrarily disadvantaged relative to the reference biologic by the shared ASP system. This policy prioritizes pricing for the reference biologic relative to biosimilars by giving the reference product its own HCPCS code. Meanwhile it treats biosimilars as if they are interchangeable generic drugs, which they are not. This separate treatment is arbitrary because differences between the reference biologic and its biosimilars are likely neither more, nor less relevant than differences among biosimilars. However, imposing a shared ASP reimbursement for biosimilars introduces a number of distortions that are likely to hinder competition. As noted above, it creates a disincentive for physicians to use a biosimilar instead of the reference product. The price dynamics and product demand under shared ASP are also inherently less predictable. These factors will contribute to reduced viability of biosimilar investment, a reduction in entry, and ultimately less competition.

Eliminating shared HCPCS codes creates better incentives for manufacturers to invest and compete in biosimilars markets. This competition would elicit a broader range of products at better value, creating benefits for all stakeholders.

IV. PRICING EXAMPLES UNDER PART B

While the U.S. biosimilar market is still developing, real-world examples are available to demonstrate that assigning separate HCPCS codes to non-substitutable, yet competing products can incentivize competitive outcomes. Innovation, entry, and competition has occurred in these markets despite the higher entry barriers inherent for products applying for NDAs or BLAs. Our expectation is that greater levels of entry and competition will occur in biosimilars markets where entry costs are lower, so our examples are a conservative guide to the benefits of biosimilar competition under separate HCPCS codes.

Figure 2 below shows, for two exemplar markets studied, the change in the incumbent product's 2-year ASP growth rate after the introduction of a separately coded competitor. In both markets, the growth rate drops dramatically after the introduction of a non-substitutable competitor product. We explore competition in these markets in the remainder of this section.

Figure 2: Summary of growth rate change after entry of a separately coded competitor

Indication	Incumbent	Entrant	Reduction in 2-year ASP growth rate after enrty	% reduction in 2-year ASP growth rate after entry
Macular degeneration	Lucentis	Eylea	1%	>100%
Cervical dystonia	Myobloc	Dysport	18%	85%

IV.A. Age-related macular degeneration products

Lucentis was a leading pharmaceutical treatment for age-related macular degeneration (AMD) until 2011 when a second product (Eylea) was introduced. Although approved under a separate NDA, and not considered interchangeable with Lucentis, Eyelea nevertheless shares indications and competes with Lucentis as a treatment for AMD. Because they do not share the same HCPCS code, their ASPs are not combined. Nevertheless, Eylea came to market at a lower price, and appears to have caused the ASP of Lucentis to drop as well.

IV.A.1. Background

AMD is the leading cause of vision loss among people age 50 or older. AMD occurs when the macula, a small spot near the center of the retina responsible for letting people see objects that are straight ahead, is damaged.[11] A person with AMD will maintain peripheral vision, but will lose the ability see fine details of what is directly in front of them. Wet AMD is a less common but more serious form of AMD where abnormal blood vessels grow under the retina. These vessels can cause scarring to the macula and accelerate vision loss (relative to dry AMD).[12]

The most common treatment for wet AMD is anti-vascular endothelial growth factor (VEGF) therapy; periodic injection of an anti-VEGF chemical into the eye. VEGF molecules support the growth of new blood vessels; anti-VEGF molecules do the opposite, inhibiting the formation of new blood cells. Thus, the anti-VEGF injection inhibits the formation of the abnormal blood vessels that lead to scarring of the macula associated with wet AMD.[13, 14]

IV.A.2. Lucentis (ranibizumab)

Lucentis is the brand name for injectable ranibizumab, an anti-VEGF biologic blood vessel growth inhibitor. The FDA approved Lucentis's NDA for treatment of wet AMD on June 30, 2006. Lucentis would go on to be approved for additional indications in 2010, 2012, 2015, and 2017.[15]

For the purpose of treating wet AMD, the suggested dosing is one 0.5 mg (0.05 mL) injection of Lucentis a month.[16]

IV.A.3. Eylea (aflibercept)

Eylea is the brand name for injectable aflibercept, an anti-VEGF biologic blood vessel growth inhibitor. Eylea received a recommendation for approval in June 2011 and was formally approved by the FDA for treatment of wet AMD on November 18, 2011. Eylea was subsequently approved for two other indications in 2014 and 2015.[17]

11 National Eye Institute (NEI), "Facts About Age-Related Macular Degeneration," accessed Oct. 5, 2017, https://nei.nih.gov/health/maculardegen/armd_facts.

12 American Academy of Ophthalmology, "What Is Macular Degeneration?," accessed Oct. 5, 2017, https://www.aao.org/eye-health/diseases/amd-macular-degeneration.

13 American Macular Degeneration Foundation, "Macular Degeneration Treatments," accessed Oct. 5, 2017," https://www.macular.org/treatments.

14 While not discussed here, Avastin is also used, off-label, to treat wet AMD. This treatment has been documented prior to the relevant price competition observed in our case study (See Adinoyi O. Garba and Shaker A. Mousa, "Bevasiranib for the Treatment of Wet, Age-Related Macular Degeneration," Opthamology and Eye Diseases, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3661434/pdf/oed-2-2010-075.pdf). Research suggests that, despite being dramatically cheaper than Lucentis and Eylea, some physicians prefer the aforementioned therapies over Avastin for clinical reasons. For example, Avastin, in order to treat wet AMD, must be processed by a compounding pharmacy, which may introduce additional risk in administering the product to a patient (See American Academy of Ophthalmology, "Avastin, Eylea and Lucentis – What's the Difference?," accessed Oct. 5, 2017, https://www.aao.org/eye-health/diseases/avastin-eylea-lucentis-difference). Thus, for purpose of evaluating price competition, Eylea and Lucentis are the relevant competitors among products with an on-label indication to treat wet AMD.

15 These indications (in chronological order) were: macular edema following retinal vein occlusion, diabetic macular edema (DME), diabetic retinopathy in people with DME, myopic choroidal neovascularization, and diabetic retinopathy. https://www.drugs.com/history/lucentis.html.

16 U.S. Department of Health and Human Services Food and Drug Administration, "LUCENTIS label," available at https://www.gene.com/download/pdf/lucentis_prescribing.pdf.

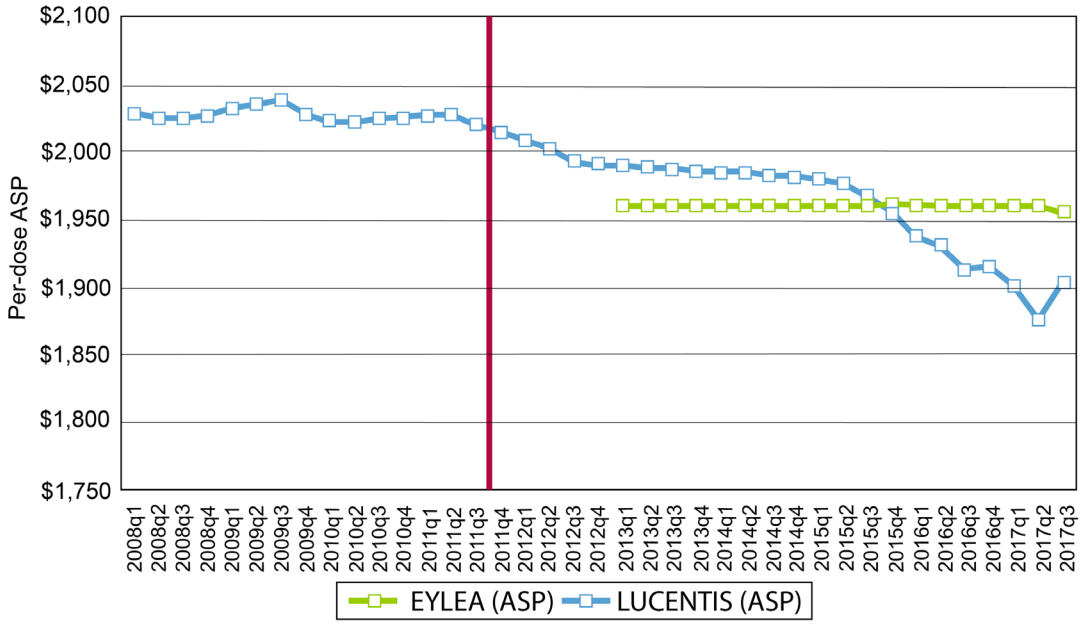
17 These indications being (in chronological order): DME and diabetic retinopathy in patients with DME. Drugs.com, "Eylea Approval History," accessed Oct. 5, 2017, https://www.drugs.com/history/eylea.html

For the purpose of treating wet AMD, the suggested dosing is one 2 mg (0.05 mL) injection of Eylea a month.[18]

IV.A.4. Analysis

Figure 3 below shows the ASPs and Lucentis and Eylea.

Figure 3: ASPs for Lucentis and Eylea

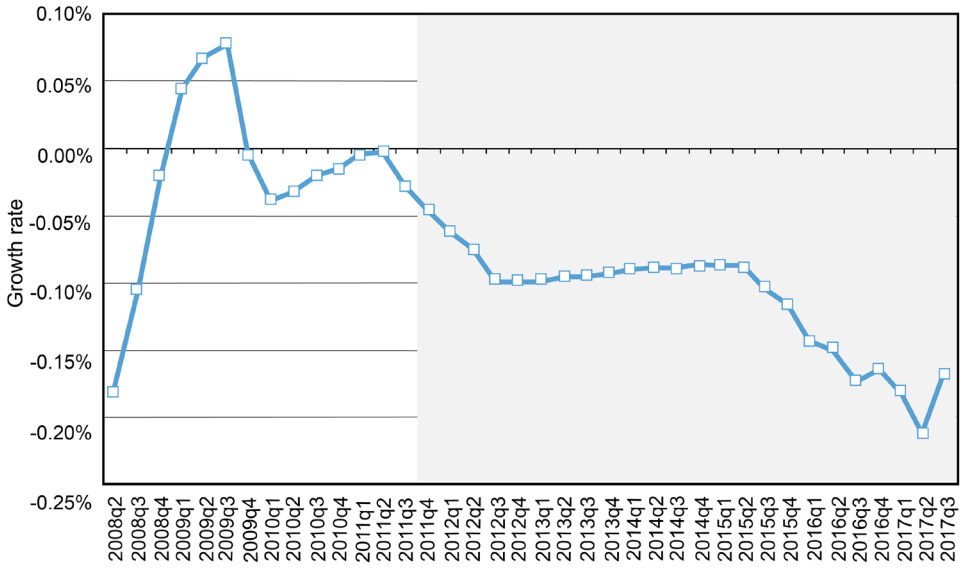


Source: ASP data

Prior to the FDA approval of Eylea (denoted by the red line in the chart above), Lucentis's price was holding relatively constant. Around the time that Eylea was recommended for approval (June 2011) and by its subsequent FDA approval (November 2011), Lucentis's price began to decline. Figure 4 below shows the changes in Lucentis's compounded growth rate (CGR) through time, highlighting the period after Eylea's FDA approval.

18 U.S. Department of Health and Human Services Food and Drug Administration, "EYLEA label," available at https://www.regeneron.com/sites/default/files/EYLEA_FPI.pdf.

Figure 4: CGR of Lucentis ASP



Source: ASP data
Note: Compounded growth rate is calculated quarterly with 2008Q1 as the base period

As shown above, Lucentis's ASP was consistently decreasing in the period after Eylea's FDA approval.

IV.B. Cervical dystonia products

Myobloc was the first FDA-approved treatment for cervical dystonia in the United States. Dysport, a similar botulinum toxin product was subsequently approved in 2009 under a separate BLA for the treatment of cervical dystonia. Dysport entered at a substantially lower price than Myobloc. Although the price of Myobloc briefly jumped prior to the entry of Dysport, the pace of Myobloc's price increases subsequently slowed substantially. This example, like the AMD example above, illustrates how competition can confer both the benefit of choice among products and price competition without a need for shared HCPCS codes.

IV.B.1. Background

Cervical dystonia, also known as spasmodic torticollis, is a painful disorder in which the neck muscles contract involuntarily, causing abnormal movements and awkward posturing of the head and neck. Most cases of cervical dystonia have no identifiable underlying causes, though in some instances, it can be brought about by secondary causes such as physical trauma.[19]

Botulinum toxins are a common treatment option used to relieve the symptoms of cervical dystonia. This treatment option works by blocking the nerve signals that cause uncontrollable tightening and muscle movements.[20]

19 Dystonia Medical Research Foundation, "More Info: Cervical dystonia," accessed Oct. 5, 2017, https://www.dystonia-foundation.org/what-is-dystonia/forms-of-dystonia/focal-dystonias/cervical-dystonia/more-on-cervical-dystonia.

20 Mayo Clinic, "Cervical dystonia," accessed Oct. 5, 2017, http://www.mayoclinic.org/diseases-conditions/cervical-dystonia/home/ovc-20260698.

IV.B.2. Myobloc (rimabotulinumtoxinB)

Myobloc was the first FDA-approved treatment for cervical dystonia in the United States. It is also the only botulinum toxin type B product commercially available, intended to reduce the severity of abnormal head positioning position and neck pain associated with the disorder.[21] Myobloc is administered as an injection directly into the affected area, and the medication's only indication lies in the treatment of cervical dystonia.[22]

The standard dose for treating patients with cervical dystonia using Myobloc is between 2,500 and 5,000 units divided among the affected muscles.[23]

IV.B.3. Dysport (abobotulinumtoxinA)

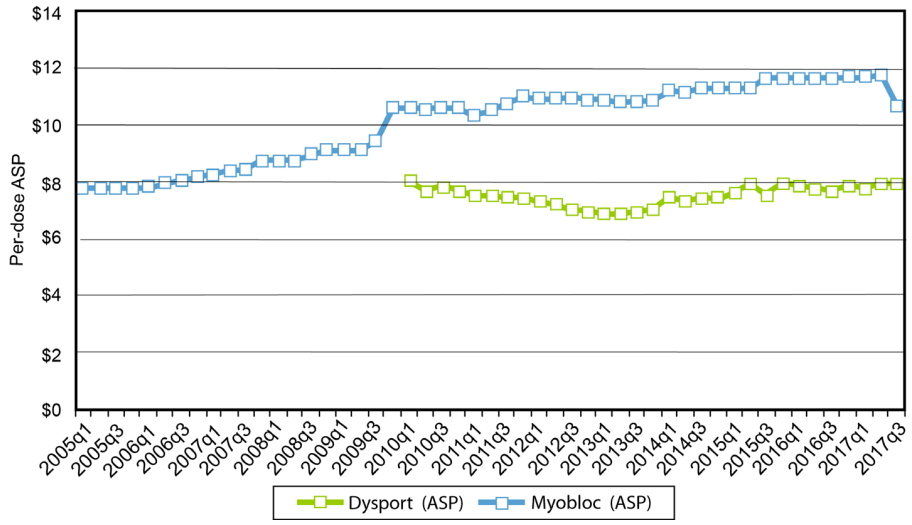
Dysport is a commonly used botulinum toxin product used to relieve the symptoms of cervical dystonia. The medication typically comes as a powder to be mixed with a liquid and is directly injected into the affected muscles.[24] The FDA approved Dysport to treat cervical dystonia on April 30, 2009. Dysport is currently approved for the treatment of several indications.[25]

The standard dose for treating patients with cervical dystonia using Dysport is 500 units divided among the affected muscles.[26]

IV.B.4. Analysis

Figure 5 below shows the ASPs of Myobloc and Dysport.

Figure 5: ASPs for Dysport and Myobloc



Source: ASP data

21 Thomas J. Walker MD and Steven H. Dayan MD, "Comparison and Overview of Currently Available Neurotoxins," ClinicaLAesthetic, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3935649/pdf/jcad_7_2_31.pdf.

22 U.S. Department of Health and Human Services Food and Drug Administration, "MYOBLOC," available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/botelan120800lb.pdf.

23 Myobloc, "About Myobloc," accessed Oct. 5, 2017, http://www.myobloc.com/myobloc/hcp/about_myobloc/dosing_admin.aspx.

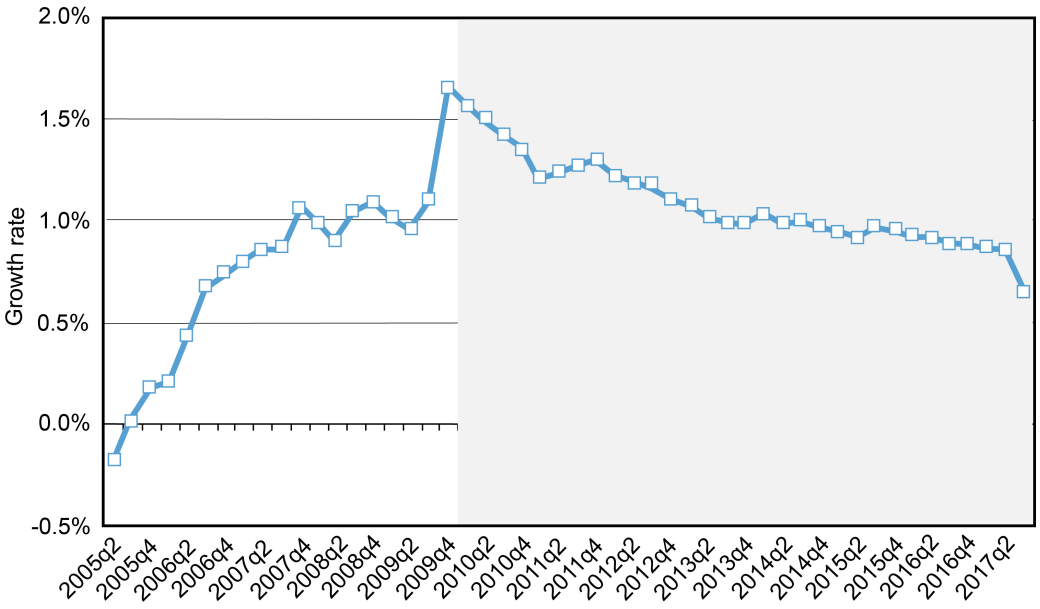
24 Medline Plus, "AbobotulinumtoxinA Injection," accessed Oct. 5, 2017, https://medlineplus.gov/druginfo/meds/a609035.html.

25 These indications include: cervical dystonia, limb spasticity, and appearance improvements in moderate to severe glabellar lines. U.S. Department of Health and Human Services Food and Drug Administration, "DYSPORT label," available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125274s107lbl.pdf.

26 Dysport, "DYSPORT (abobotulinumtoxinA) Dosing and Dilution Guide," available at https://dysporthcp.com/docs/pdfs/Dosing_and_Dilution_Brochure.pdf.

Prior to the introduction of Dysport into the market, Dysport's price was steadily increasing. Beginning in 2010q1, however, Dysport's ASP began holding relatively constant.

Figure 6: CGR of Myobloc ASP



Source: ASP data
Note: Compounded growth rate is calculated quarterly with 2005Q1 as the base period

As shown in Figure 6 above, the introduction of competition into the market led to a declining CGR for Myobloc's ASP.

V. CONCLUSION

We recommend the elimination of the current shared ASP reimbursement and propose that biosimilar products be put on equal economic footing with both each other and the reference biologic by giving them separate HCPCS codes and ASPs. Maintaining separate HCPCS coding and reimbursement for the reference biologic while forcing biosimilars to share a common HCPCS code and identical Part B reimbursement arbitrarily causes market distortions that negatively impact biosimilar adoption by physicians and inhibit long-run investment in biosimilars and reduce entry of new products. This means fewer benefits from competition, such as lower prices, greater product choice, and better patient outcomes. Experience in Medicare Part B has shown that separately coding products can incentivize product entry and price competition.

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