Health Care
Communiqué

(Gleevec®) Imatinib Mesylate

A breakthrough generic for a breakthrough drug

By Tasmiya Khan, PharmD Director

Solid Benefit Guidance
ARTHUR J. GALLAGHER & CO.

Imatinib Mesylate 100mg and 400mg (Gleevec®) is available as a generic drug as of February 1, 2016.

Gleevec® was approved by the US Food and Drug Administration (FDA) in 2001 as the first targeted cancer drug. It is used for the treatment of certain types of cancer, including Chronic Myelogenous Leukemia (CML), and is currently sold by Novartis Pharmaceuticals Corporation. Gleevec® is Novartis' best-selling drug, with $4.7 billion in sales in 2014. In fact, an Express Script report this year showed Gleevec® held the largest piece of the U.S. cancer drug market with a 12.5% market share.[1]

On December 4, 2015, the Food and Drug Administration (FDA) approved the first generic version of the drug Gleevec®, also known as, Imatinib Mesylate. The generic drug is made by Sun Pharmaceutical Industries Ltd. of India, who was the first to file an Abbreviated New Drug Application (ANDA) and therefore received exclusive rights for six months of sales beginning on February 1, 2016[2]. Generic drug applications are termed "abbreviated" because instead of having to show data to establish safety and effectiveness, generic drug manufacturers need to show that their product is bioequivalent to the branded medication. Bioequivalent means that the generic version must deliver the same amount of active ingredients into the patient's bloodstream[3]. Imatinib Mesylate as a generic alternative for Gleevec® is rated "AB", which means it is therapeutically equivalent to the branded drug[4]. This is important for stakeholders, including payers and caregivers, as it offers an option for patients that is presumably as safe and effective as Gleevec® but more cost-effective.

400 mg
10K/month

100 mg
3K/month

Gleevec® 400mg currently costs about $10,000 a month and Gleevec 100mg is about $3,000 per month[5]. The price of generic Gleevec® is not expected to fall until after the period of six-month exclusivity, which will end in August 2016. Currently, there is one generic manufacturer, with the hope that there will be more generic manufacturers to drive down the cost of the generic. The cost of the generic is not available at this time.

SBG Perspectives

With Gleevec® becoming a generic, and especially post the six-month exclusivity, payers have an opportunity to evaluate formulary placements and leverage the use of this generic drug. For the purposes of an AB-rating and the generic equivalent, the key advantage is that it allows the pharmacist/pharmacy to automatically substitute for the brand at point of sale, without needing to call the doctor unless the doctor specifically indicates a need for the brand version of the medication. In fact, oncologists have expressed positive feedback on the generic availability of Gleevec® in hopes to drive down healthcare costs. With that, payers should consider using utilization management strategies to promote generic use. Suggested strategies include adding Prior Authorization (PA) or Step Edit (ST) to the brand drug. A PA could require prescribers to justify the use of the brand version of a drug in cases where safe and effective alternatives exist at a cheaper cost. Step Edits (ST) could require patients to at least try the generic drug first before covering a brand drug. In fact, most formularies are designed to promote generic use in general, by either less or no coverage of branded medications.

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Independent Auditor Validations

By Treesie Farmer, CFE, CHC Director of Compliance

On November 12, 2015 the Centers for Medicare and Medicaid Services (CMS) released the HPMS memo entitled, Independent Auditor (IA) Validation Process for Medicare Advantage and Prescription Drug Plan Program Audits.

Beginning with the 2015 program audit results and going forward, CMS will require a Plan Sponsor to hire an IA to validate if the deficiencies discovered during a CMS full or partial program audit have been corrected. CMS will inform the Sponsor in the final audit report whether an IA is required. The purpose of a validation review is for the Sponsor to demonstrate corrections of the conditions of non-compliance identified in the final CMS audit report and to serve as the basis for the CEO's attestation that the conditions are corrected and are not likely to recur.

CMS provided instructions and clarification on the steps of the IA validation process as follows

Step 1: Hiring an IA

CMS will not provide recommendations on IA firms. However, the IA must meet the following requirements to be acceptable to CMS:

The Sponsor must attest that the IA is independent and has no conflicts of interest, meaning the IA is not employed, contracted, sub-contracted, represented or considered to be a first-tier, downstream or related entity (FDR) by the Sponsor.

The IA must have subject matter expertise in the areas of Medicare Part C & Part D that will be subject to review in the validation.

CMS recommends that Sponsors obtain bids and select an IA early in the post-audit phase because the process must be completed before a Sponsor will be eligible to enter the validation phase of its program audit. Sponsors may use the same IA to validate both sanctioned and non-sanctioned conditions and may conduct those validations separately or together.

Step 2: Developing a Validation Work Plan and Timeline

CMS recommends the Sponsor and IA meet to discuss the scope of the validation. The Sponsor should provide the final CMS audit report and its Corrective Action Plans (CAPs) to assist the IA in understanding what needs to be evaluated during the validation. The IA will create a validation work plan that details how it will conduct the validation and a validation schedule that identifies key milestones in the validation process. CMS requires the validation work plan test compliance outcomes of sampled cases and/or an entire universe of data. Validation should not be just a review of policies and procedures or processes but rather a test of the effectiveness of the CAPs and whether the Sponsor's transactions now comply with CMS requirements.

The IA should test transactions beginning at the "clean" period. CMS defines the "clean" period as the period of time where a Sponsor believes its operations are free from any audit-related deficiencies. The Sponsor will operate in the "clean" period until enough time has passed for a complete universe to be submitted for validation. A complete universe is the same time period provided in the current CMS Program Audit Protocols for the applicable subject matter area. Enough transactions should be generated from the "clean" period for the IA to sufficiently test whether the Sponsor has corrected the deficiencies.

Once the Sponsor and IA agree on the validation work plan and schedule, the Sponsor will submit these documents to CMS and schedule a call with CMS and the IA. On the call with CMS, IA must walk through the validation work plan, explain the proposed duration of the process, and answer CMS questions and/or make CMS requested changes. After the call, the IA and Sponsor will update the final validation work plan and submit it to CMS for final approval.

Step 3: Conducting the Validation

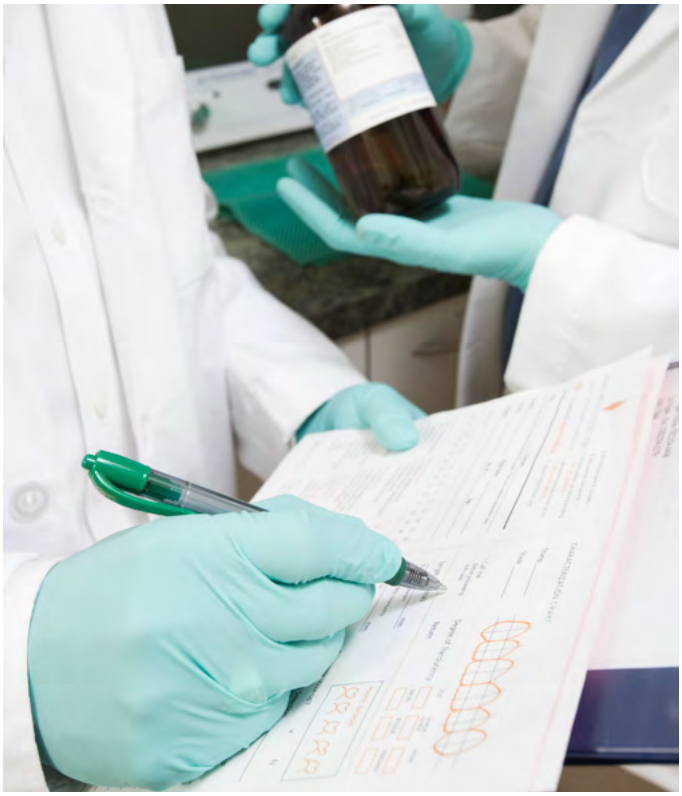
IAs must conduct validations according to the work plan approved by CMS. (Step 2) The Sponsor must provide unrestricted access to information related to the areas under validation and respond to the IA's request for additional information. Before selection and/or reviewing of sample cases, the IA must conduct data integrity tests of universe submissions to ensure they are complete and accurate. If the IA can't determine if the data universes are complete and reliable, the IA should not proceed and contact CMS for further guidance.

If the IA discovers sample case failures, the IA should request the Sponsor review the failed cases and determine how many beneficiaries have been impacted. If additional beneficiaries are affected, a beneficiary impact analysis (BIA) must be provided to the IA for inclusion in the validation report. The IA should validate the accuracy of the BIA. The Sponsor must respect the independence of the IA and not attempt to inappropriately influence how the validation is conducted or the findings derived.

Step 4: Reporting the Results of the Validation Audit

The IA will draft a validation report of the findings from the validation. The IA should not make any recommendations to CMS about whether violations or audit conditions have been adequately corrected. The IA should report the outcomes of the sample cases and universes reviewed.

The IA will submit the validation to the Sponsor for their thorough review of the results and discussions with the IA to address any disagreements or responses. If the Sponsor decides it has sufficiently corrected its audit-related deficiencies based on the IA's validation report, it must attest within HPMS that all the deficiencies have been corrected and are not likely to recur. The attestation must be included with the IA's report and any additional information the Sponsor wants CMS to consider. If the Sponsor decides it has not adequately corrected all the deficiencies, it should contact its CMS Validation Lead to discuss issues that need further correction. The Sponsor must implement new CAPs and repeat the validation process until the CEO can attest within HPMS that all findings have been corrected.



Step 5: CMS Review of the Validation Report and Other Information

CMS will review the IA's validation report and additional information and will likely request a follow-up call with the IA and the Sponsor to ask questions. Once CMS has all the information needed, CMS will make a determination about whether to close the audit process. CMS will schedule a call with the Sponsor's CEO and Medicare Compliance Officer to inform them of CMS' decision and next steps, or issue an audit close-out notice.

CMS Part D Prescriber Enrollment Requirements - Updated Technical Guidance

CMS released an HPMS Memo titled, "Medicare D Prescriber Enrollment Technical Guidance," on December 29, 2015. This memo included updated information regarding Part D Prescriber Enrollment Requirements which go into effect June 1, 2016.

By Sandy Om, Area Vice President of Medicare Consulting

In an effort to promote quality and combat fraud and abuse, CMS will enforce a new requirement regarding Prescriber Enrollment starting on June 1, 2016. The new regulation will require that all prescriptions to be coverable under Part D, physicians, dentists and other eligible professionals who write Part D drug prescriptions must:

- Be enrolled in Medicare in an approved status or
- Have validly opted out of Medicare

In the recently released "Medicare D Prescriber Enrollment Technical Guidance," CMS provides technical guidance that should be applied once the Part D Enrollment Requirement is enforced beginning on June 1, 2016. CMS addresses topics that required further guidance and also clarified comments that were received.

The topics that CMS covers in the memo include:

- Part D Prescriber Enrollment Requirement- outlines the new actions that will be required upon receipt of a pharmacy claim or a beneficiary request for reimbursement.
- Other Authorized Prescribers (OAP)- CMS will continue to identify categories of providers that might meet the definition of an OAP (i.e. pharmacists and naturopaths).
- Provisional Drug Supply and Written Notices- provides information on three-month provisional fill requirements. In addition, guidance on notices to beneficiaries and prescribers is outlined within the memo.
- "Drug" for Purposes of Provisional Supply- this is defined by the generic name, dosage form, and way of administration.
- Direct Member Reimbursement- beneficiary's request for reimbursement of out-of-pocket expenses should not be denied based on the basis of a prescriber's status. If the prescriber is not enrolled or opted out, and is not an OAP, the sponsor must cover a provisional supply of the drug and send the required beneficiary written notice.
- Data Files- Part D sponsors are expected to keep current with the Medicare Individual Provider List and NPPES downloadable data files for proper Part D claim adjudication and to avoid issues with PDE submission.
- Deceased Prescribers- if a deceased Medicare prescriber is enrolled or opted out, the deceased prescriber's existing prescriptions are coverable under Part D, so long as the deceased prescriber's NPI is still effective on the Medicare Individual Provider file (assuming the prescriptions are valid under applicable law).
- Dual-Eligible Beneficiaries Enrolled in a Part D Plan- if a Part D drug is not covered based on the Medicare Part D Prescriber Enrollment Requirement, the drug will also not be coverable and is ineligible for federal matching funds under Medicaid for dual eligible beneficiaries (this is due to the fact that the drug could be coverable under Part D if the prescription were written by a prescriber who is enrolled, opted-out, or an OAP).

Additional items highlighted within the memo:

If a claim is rejected only based on the prescriber enrollment issue after a beneficiary has received a provisional supply, the "569" code should not be returned. The "569" code is the National Council for Prescription Drug Programs (NCPDP) response code for the delivery of the standardized pharmacy notice, "Medicare Prescription Drug Coverage and Your Rights." In these scenarios, directing the beneficiary to the coverage determination process will not resolve the issue with the prescriber. If the claim contains additional reject codes that trigger the "569" code transmission, the network pharmacy should deliver the standardized pharmacy notice.

When adjudicating a pharmacy claim where a beneficiary receives a provisional drug supply and individualized written notice, but the drug is off-formulary and the transition requirements are also triggered under Part D transition fill guidance, the beneficiary should not receive more than the applicable transition supply of the drug, unless a formulary exception is approved.

What should plans be doing?

- Review the HPMS Memo titled, "Medicare D Prescriber Enrollment Technical Guidance," in detail.
- Monitor reports on prescribers who have not yet enrolled or opted out.
- Communicate with prescribers who have not yet enrolled or opted out.
- Review volume of claims rejects that would occur when this goes into place.
- Ensure that the systems will be ready to adjudicate these claims appropriately (provisional fill beginning June 1, 2016 and rejections starting September 1, 2016).
- Confirm member and prescriber communications will be implemented timely.
- Make sure that customer service representatives are trained in this new requirement so they are able to address beneficiary questions.

The Prescriber Enrollment process will allow CMS to validate a prescriber's credentials and will prevent unqualified physicians from prescribing Part D drugs. In addition, if a physician/practitioner (including dentists) decides to opt out of Medicare, they will not be eligible to receive reimbursement for items and services covered by traditional Medicare or a Medicare Advantage plan, including those covered as supplemental benefits, except for emergency and urgent care services as permitted by regulations. Part D sponsors should continue to actively monitor the progress of enrolled prescribers to minimize negative impact to their enrollees.

Biosimilars - Current Landscape, Pipeline and Reimbursement Perspectives

Solid Benefit Guidance
ARTHUR J. GALLAGHER & CO.

By Lynn Nishida, R.Ph. Assistance Vice President Pharmacy Services

In 2015, Zarxio® (filgrastim-sndz), which is a biologic, became the first biosimilar approved by the U.S. Federal Food and Drug Administration (FDA).[1] Zarxio® is similar to, but not an exact copy of, Neupogen® (the biologic reference product).

Biologics are composed from living substances resulting in complex medication products. Traditional medications, which are chemical substances, can be copied to an exact generic version. However, biologics cannot be exactly copied due to their complex makeup.

The FDA Biosimilar Pathway was developed under the Patient Protection and Affordable Care Act (ACT). This approval pathway, known as the 351(k) approval pathway, is an abbreviated licensing mechanism to bring biologics to the market that are similar, but not exact, to an FDA biologic (referred to as the reference product), creating competition and potentially improving product quality.[2]

Therefore, a biosimilar is similar, but not exact, to a reference biologic product. The FDA standards for approving biosimilars are significantly different than those for the approval of generics.

Being far more complicated to produce, biosimilars are not expected to bring the large discounts like standard generics, but stir favorable market competition among very expensive specialty biologic medications to drive lower prices.

The cost savings potential of biosimilars has been estimated to be up to $44.2 billion (or 4 percent of total spending on biologics over a course of 10 years).[4]

- These savings will largely depend on existing market dynamics, number of competing products, as well as biosimilar manufacturers, who in lieu of lowering their list price less than the biologic reference product, may opt to negotiate unique discounts with payers in the form of rebates and/or other contractual arrangements with payers for favorable discounts.
- Zarxio®'s list price is about 15% less than its reference product, Neupogen® that runs about $3,000 for 10 injections.
- This appears consistent with European experience where biosimilars have been available for quite some time and reported discounts for biosimilars are running on average typically less than 25 percent (of their reference products).[3]

Pharmaceutical manufacturers are investing significant dollars in pursuing biosimilar development for some very well-known specialty biologics. (See Table 1).

Pfizer/Hospira is observed in having one of the largest biosimilar pipelines spanning 10 different products.

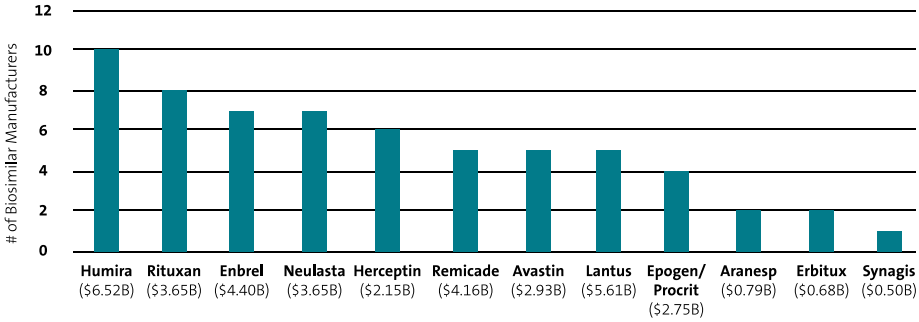
Table 1: Key Biosimilar Manufacturer Sponsors – Pipeline

Key Biosimilar Sponsors[1]	Humira (adalimumab)	Rituxan (rituximab)	Enbrel (etanercept)	Neulasta (pegfilgrastim)	Herceptin (trastuzumab)	Remicade (infliximab)	Avastin (bevacizumab)	Lantus (insulin glargine)	Epogen (Epoetin Alfa)	Aranesp (darbepoetin)	Erbitux (cetuximab)	Sunagis (palivirumab)	Target Annual US
# of Sponsors	10	8	7	7	6	5	5	5	4	2	2	1	$235.23B
Hospira/Pfizer	×	×	×	×	×	×	×		×		×	×	$31.39B
Merck/Samsung	×	×	×		×	×		×					$26.49B
Mylan/Biocon	×		×	×	×		×	×					$25.28B
Amgen/Actavis	×	×		×	×	×					×		$20.09B
Sandoz (Novartis)	×	×	×	×					×				$20.97B
Dong-A/Meiji	×		×	×	×					×			$17.52B
Biogen	×		×			×							$15.08B
Boehringer Ingel.	×	×					×						$13.10B
Celltrion		×			×	×							$9.95B
Baxter	×		×										$10.93B
Momenta	×						×						$9.46B
Lupin				×				×	×				$12.01B
Eli Lilly		×						×					$9.26B
Dr. Reddy/Merck		×		×						×			$8.09B
Wockhardt								×	×				$5.61B
Teva				×					×				$6.40B

1 Many molecules are co-developed and some smaller biosimilar developers may not be included.
2 Targeted Annual US. $ Revenue is based on the sum of 2014 US sales for the originator product, not the expected market share for the biosimilar.

Humira® is the largest target for competition, with 10 manufacturers in varying stages of biosimilar development for this product. (See Graph 1)

Graph 1: # of Manufacturer Sponsors Developing Biosimilars for Key Specialty Biologics (U.S. Annual Revenue in $ Billions)*



*Annual US Revenue is based on 2014 US market sales for the specialty biologic reference product (innovator). This is not the expected market share for the biosimilar.

Predicting the Next Biosimilar

Since the approval of Zarxio® (filgrastim-sndz), the FDA has made slow progress toward approving more biosimilars.

This is likely due to the approval process for biosimilars being new in the United States.

Overtime, as experienced in other countries, the approval process is hoped to mature and become more standardized, facilitating faster and more approvals.

Table 2 provides details on five biosimilars that have filed applications with the FDA.

Of these five, Celltrion's Remsima® (biosimilar for Remicade®) was originally targeted for an approval decision by June 8, 2015. However, the FDA's Advisory panel that was originally scheduled to review Remsima® in March of 2015, postponed this meeting "due to information requests pending with the sponsor of the application."[8]

Hospira's filing for Retacrit®, a biosimilar version of Epogen® and Procrit®, was issued a "complete response" letter by the FDA citing to the company that it would need to provide additional information to the FDA to complete the application for approval.[10]

Ultimately, these delays air uncertainty in predicting when the next biosimilar will hit the market and whether the 351(k) approval pathway for biosimilars will be all too complicated to expedite the availability of biosimilars to market.

Reimbursement and Formulary Processes for Biosimilars

Despite this lull of new biosimilars to market, payers continue to plan out strategies for how biosimilars are handled under their current formulary processes for coverage and reimbursement

The Centers for Medicare and Medicaid Services (CMS) issued several guidance documents to address the handling of

Table 2: Biosimilars – Filed Applications and FDA Review

Biosimilar	Biosimilar Manufacturer	Reference Product	Use	FDA Application	Market approval prediction*
infliximab (Remsima)	**Celltrion**	**Remicade** (Janssen)	**Inflammatory Conditions**	**Accepted 8/12/2014**	Originally forecasted for 6/8/15. FDA Panel Review postponed in 2/2015
pegfilgrastim (Grastofil)	**Apotex**	**Neulasta** (Amgen)	**Increase white blood cells to fight infection**	**Accepted 8/12/2014**	**10/2016**
epoetin alfa (Retacrit)	**Hospira/Pfizer**	**Epoge** (Amgen) **Prori** (Janssen)	**Increase red blood cells in anemia**	**Accepted 8/12/2014** Issued Complete Response Letter 10/27/15	???
etanercept	**Sandoz**	**Enbrel** (Amgen)	**Inflammatory Conditions**	**Accepted 8/12/2014**	**8/2016**
adalimumab (ABP 501)	**Amgen**	**Humira** (AbbVie)	**Inflammatory Conditions**	**Accepted 8/12/2014**	—

*Based on standard 10 month review period. Subject to change and highly contingent on FDA decision to postpone/delay review and/or issuance of complete response letter for additional information needed from manufacturer.

biosimilar products for purposes of reimbursement and rebates under Medicare (Part B and D) and the Medicaid Rebate Program.[5-7]

Because biosimilars do not meet standard definitions of a "generic" or a "multiple source" medication, CMS generally treats biosimilars in most cases like a single source (innovator) medication for purposes of rebates and reimbursement. This subjects biosimilars to:

- Separate coding from its innovator reference product.
- Potential for higher copayments for members.
- Higher Medicaid rebate obligations for manufacturers than if they had been characterized as non-innovator products.

While CMS guidance is the first step towards "consistent" reimbursement policies and formulary review processes, payers need to be aware of particular circumstances where coverage of biosimilars may not follow conventional means for reimbursement, discounts, rebates and/or formulary processes.

For Example

The Affordable Care Act established the Discount Program by adding sections 1860D-43 and 1860D-14A of the Social Security Act and defines applicable drugs that are discounted in the coverage gap under Medicare Part D. When defining "applicable drugs" that are discounted under the Discount Program, the statute specifically excludes biological products receiving FDA approval under subsection (k) of section 351 of the Public Health Service Act. Consequently, biosimilars are non-applicable drugs for purposes of establishing coverage gap cost sharing under the basic Part D benefit, and are not discounted or otherwise subject to Discount Program requirements.[9]

As an unintended consequence, payers may lean toward the reference medication (which gap discounts would apply) as preferred products over biosimilars, in order to reduce member out of pocket while in the donut hole.

The following two tables provide summaries of pertinent information about biosimilars that payers need to consider for their reimbursement and formulary processes across their various lines of business.

Table 3 provides the depiction of how biosimilars are generally recognized and handled under CMS guidance compared to that of the reference biologic or a generic medication, under Medicare (Part D and B) and Medicaid. Certain provisions may also apply to the first marketed biosimilar versus subsequent ("follow-on") biosimilars that are later approved by the FDA for the same reference product.

Table 4 provides additional details and Solid Benefit Guidance (SBG) commentary.

To date, there are no biosimilars that have been approved by the FDA as an "interchangeable" biosimilar.

Designation as an "interchangeable" biosimilar would allow pharmacists, (depending on individual state laws), the ability to automatically substitute the biosimilar to its reference product.[2]

CMS guidance is broadly written to apply to all biosimilars. However, CMS has noted it may issue additional reimbursement guidance in the future to specifically address "interchangeable" biosimilars.

Table 3: Reimbursement and Formulary Processes – How Biosimilars are Handled? (Medicare Part D, Medicare Part B, and Medicaid)[5-7]

Line of Business	When a biosimilar (or follow-on-biosimilar(s)* come to market, these products will follow reimbursement and formulary processes similar to:					
	For First Marketed Biosimilar			For Follow-on Biosimilar(s)		
	Reference Biologic	Generic Drug	Unique Biosimilar Treatment	Reference Biologic	Generic Drug	Unique Biosimilar Treatment
Medicare Part D (Part D Requirements for Biosimilar, CMS Memo dated March 30, 2015						
Transition Fill	X			X		
P&T Committee Formulary Review Timeline	X			X		
USP Coverage Requirements		X			X	
LIS Cost Sharing	X			X		
Coverage Gap Discount		X			X	
Mid-Year Formulary Changes	X			X		
Protected Classes						
Medicare Part B (Reference: MLN Matters #: SE1509, CMS Final Rule October 30, 2015)						
Coverage	X			X		
Coding	X					X Noninterchangeable biosimilars grouped together under 1 code
Payment			X All biosimilars grouped together under 1 payment calculation and billing code.			X All biosimilars grouped together under 1 payment calculation and billing code.
Medicaid						
Rebates	X			X		

***Follow-on biosimilar refers to all subsequent biosimilar(s) that come to market after the first marketed biosimilar for a single reference biologic product.**

Table 4: Biosimilars Reimbursement and Formulary Processes – Key Details and SBG Commentary (Medicare Part D, Medicare Part B, and Medicaid)[5-7]

Line of Business	Summary of Key Details & SBG Commentary
Medicare Part D[5]	**Formulary Processes** • For USP coverage requirements, biosimilars and their innovator reference product are not considered different medications in satisfying the two-medication formulary requirement. • Mid-year addition of a biosimilar and removal of a reference biologic are considered non-maintenance changes requiring CMS approval. • Pharmacy and Therapeutics Committees must review newly approved biosimilars according to existing formulary management requirements, which include making these products for formulary status within 180 days for standard review, or 90 days in the case of medications in protected classes. **Transition Fills** Part D plan sponsors must treat a biosimilar and the reference product as different medications for the purposes of fulfilling transition fill requirements. **Low Income Subsidy (LIS)** Biosimilars do not meet the definition of a multi-source medication; therefore, biosimilars are subject to higher low income subsidy (LIS) maximum copayments. **Gap Coverage** Similar to generic medications, biosimilars are excluded from the Coverage Gap Discount Program by the Affordable Care Act (ACA); and thus considered non-applicable medications. Consequently, non-LIS beneficiaries will not receive the 50 percent discounts from manufacturers in the coverage gap. **Interchangeable Biosimilars** To date, the FDA has not designated any biosimilar as interchangeable. CMS indicates that it will issue additional guidance to address reimbursement of interchangeable products in the future.
Medicare Part B[6-7]	**Billing Code** • The first marketed biosimilar will receive an HCPCS code separate from reference product and paid at its own Average Sale Price (ASP) plus 6% of the reference product's ASP. • Until an ASP is available, the biosimilar will be paid at 106% of its own Wholesale Average Cost (WAC). • A single reimbursement price and HCPCS code will apply to all biosimilars; both the first marketed biosimilar and subsequent ("follow-on") biosimilars of a given reference product. **Interchangeable Biosimilars** CMS specifically notes in its guidance that it did not consider how interchangeability status will factor into its final payment policy, but may issue additional guidance should an "interchangeable" biosimilar become FDA-approved.
Medicaid[6-7]	Biosimilars are considered brand medications for purposes of the Medicaid Rebate calculation. CMS recommended that States take necessary steps to encourage the use of biosimilars (e.g., step therapy, prior authorization, use of preferred medication lists) for cost savings opportunities.

SBG Perspective

Biosimilars have the potential to stimulate favorable market competition to drive lower prices, provide cost savings, and improve the quality of biologic products.

Cost savings from biosimilars will have many regulatory and market driven dependencies including:

1. Despite a robust biosimilar product pipeline, the prevailing uncertainty of when the next biosimilar may be approved by the FDA.
2. The number of competing products that exist when a biosimilar comes to market.
3. Patent litigations.
4. Evolving federal (or state) guidance and policy requirements that may unintentionally steer payers away from promoting biosimilars as potentially least costly options.
5. Biosimilar manufacturers that may not necessarily market their product at a lower price, but instead negotiate discounts with payers and Pharmacy Benefit Managers (PBMs) in the form of rebates and/or other contractual arrangements that will provide discounted prices.

For payers who have contracted their rebates and pharmacy discounts for medications through a PBM, the degree of potential savings will depend on the structure of these arrangements. Please be aware that new types of rebate contracting arrangements may evolve as a result of biosimilars.

CMS guidance issued in mid to late 2015 for Medicare (Part B and D) and Medicaid will largely shape how payers reimburse, as well as handle biosimilars under their formulary processes.

SBG recommends that payers:

- For Medicare (Part B and D) and Medicaid lines of business, ensure that contracts and applicable policies align with CMS guidance on biosimilars for appropriate reimbursement and formulary processes.
- For Commercial and Exchange lines of business, work toward similar alignment of contracts and practices that will provide the best consistency across all lines of business and promote biosimilars when appropriate for their cost savings potential.
- Continually track evolving federal and state legislation pertaining to biosimilars (particularly interchangeability and substitution laws) that may vary from state to state.
- Keep vigilant on the FDA's progress on their review of biosimilars for timely planning of contracting strategies and implementation of utilization management that will likely be needed to address the next biosimilar that hits the market.

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CMS Timeline

January 1 – February 14, 2016
Annual 45-Day Medicare Advantage Disenrollment Period (MADP)

January 12, 2016
Release of the CY2017 MAO/MA-PD/PDP/Service Area Expansion Applications

January 13, 2016
Part C and D User Call - Part 1 Application Training

January 20, 2016
Part C and D User Call - Part 2 Application Training

January 31, 2016
Deadline for NOIA form submission to CMS

January 28 – February 3, 2016
Sponsors required to upload the POS rejected claims as a .txt file for CY2016 TMPA

February 17, 2016
CY2017 Applications due

February 2016
CMS releases guidance concerning updates to Parent Organization designations in HPMS

March 2016
Parent Organization Update requests from sponsors due to CMS (instructional memo to be released in February 2016)

About UL EduNeering

UL EduNeering is a division within the UL Ventures business unit. UL is a premier global independent safety science company that has championed progress for 120 years. Its more than 10,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®. In addition, UL offers a talent management suite that provides companies the ability to improve workforce skills & competencies within established role-based talent training programs to drive business performance.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council and the Duke Clinical Research Institute.

About our Authors

Solid Benefit Guidance
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Solid Benefit Guidance, LLC (SBG) is one of the nation's leading consulting firms and thought leaders in the PBM industry. With more than 130 years of collective experience in this highly complex industry, SBG provides plan sponsors and health plans an unparalleled evaluation of their compliance, pharmacy costs, performance and trends. Some of the services they offer include:

- PBM Procurement & Vendor Oversight
- Compliance Medicare/Medicaid
- PBM Auditing
- Specialty Pharmacy Management Strategy
- Clinical Consulting

SBG experts serve as UL EduNeering's Health Care Library Course authors, and contribute articles to the Health Care Communiqué.

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