Tackling the Complexities of Biosimilars Across Pharmacy Settings

This session is supported by an educational grant from Sandoz.

Faculty

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Disclosures

Dr. Lucio: Employee - Vizient

Learning Objectives

- Outline the requirements for biosimilars approval such as the clinical data package, totality of evidence, extrapolation of data, interchangeability, and substitution
- Evaluate the clinical data supporting the safety, efficacy, biosimilarity, and interchangeability of approved and late-stage biosimilars
- Describe the impact of current and emerging regulatory and legal requirements on biosimilar interchangeability designation, switching/comparability studies, pharmacovigilance, product tracking, and accessibility
- Integrate new and emerging biosimilars into clinical care plans, systems-based processes, formulary discussions, and provider/patient communication strategies

Phases of Biosimilar Market Development

G-CSF = granulocyte-colony stimulating factor.

Biosimilar Approvals to Date

	Product	Manufacturer	Date Approved	Date Marketed
1	Zarxio® (filgrastim-sndz)	Sandoz	3/6/2015	9/3/2015
2	Inflectra® (infliximab-dyyb)	Celltrion/Pfizer	4/5/2016	11/2016
3	Erelzi™ (etanercept-szzs)	Sandoz	8/30/2016	?
4	Amjevita® (adalimumab-atto)	Amgen	9/23/2016	1/31/2023 (proposed)
5	Renflexis™ (infliximab-abda)	Samsung/Merck	4/21/2017	7/24/2017
6	Cyltezo® (adalimumab-adbm)	Boehringer Ingelheim	8/29/2017	?
7	Mvasi™ (bevacizumab-awwb)	Amgen/Allergan	9/14/2017	?
8	Ogivri™ (trastuzumab-dkst)	Mylan	12/1/2017	?
9	Ixifi® (infliximab-qbtx)	Pfizer	12/13/2017	?
10	Retacrit™ (epoetin alfa-epbx)	Pfizer	5/15/2018	Pending
11	Fulphila™ (pegfilgrastim-jmdb)	Mylan	6/4/2018	Pending
12	Nivestym™ (filgrastim-aafi)	Pfizer	7/20/2018	Pending

FiercePharma [website]. https://www.fiercepharma.com/pharma/abbvie-s-humira-patents-hold-up-as-amgen-settles-2023-biosim-launch. Accessed January 17, 2018. Drugs@FDA Approved Products [website]. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm. Accessed August 27, 2018.

Known Biosimilar Pipeline for Remainder of 2018

International Nonproprietary Name	Manufacturer	Application Submitted	Estimated FDA Approval Date
Trastuzumab (CT-P6)	Teva and Celltrion	5/2017	3/2018[a]
Trastuzumab (ABP 980)	Amgen and Allergan	7/2017	5/2018[a]
Rituximab (GP2013)	Sandoz	7/2017	5/2018[a]
Trastuzumab (PF-05280014)	Pfizer	7/2017	5/2018[a]
Filgrastim	Adello Biologics	7/2017	5/2018?
Trastuzumab (SB3)	Samsung Bioepsis and Merck	10/2017	10/2018
Rituximab (CT-P10)	Teva and Celltrion	5/2018	11/2018
Adalimumab (GP2017)	Sandoz	11/2017	11/2018
Pegfilgrastim (CHS-1701)	Coherus	5/2018	11/3/2018

[a]Delayed due to receipt of complete response letter.
FDA = US Food and Drug Administration.
Pink Sheet [website]. https://pink.pharmaintelligence.informa.com/product-reviews-and-approvals/fda-performance-tracker. Accessed August 31, 2018.

Biosimilars: Legal and Regulatory Updates

FDA Biosimilar Action Plan

- 11 actions identified by the US Food and Drug Administration to:
  - Improve the efficiency of biosimilar and interchangeable biologic development and approval
  - Maximize scientific and regulatory clarity for the biosimilar development community
  - Increase understanding of biosimilars among patients, clinicians, and payors
  - Reduce gaming of FDA requirements or other attempts to unfairly delay competition
- Open public hearing: September 4, 2018

US Food and Drug Administration. Biosimilars action plan: balancing innovation and competition. July 2018:1-9. https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM613761.pdf.

Legal Updates

- AbbVie and Amgen settlement
  - AbbVie to grant nonexclusive patent licenses to Amgen
  - Amgen can launch biosimilar adalimumab in Europe on October 16, 2018, and in the United States on January 31, 2023
- AbbVie and Samsung Bioepis agreement
  - If approved, biosimilar can launch June 30, 2023
- Pfizer lawsuit against Johnson & Johnson due to anticompetitive practices related to Remicade®
- Amgen awarded $70 million for Pfizer/Hospira biosimilar infringing Epogen® patents
- Many other legal issues remain throughout the court system

Pink Sheet [website]. https://pink.pharmaintelligence.informa.com. Accessed February 5, 2018. Reuters [website]. Health News. Mathias T. April 5, 2018. https://www.reuters.com/article/us-abbvie-biogen/abbvie-samsung-bioepis-in-deal-humira-biosimilar-u-s-release-in-2023-idUSKCN1HC1SP. Accessed April 6, 2018.

What Have We Learned from Biosimilars Approved to Date?

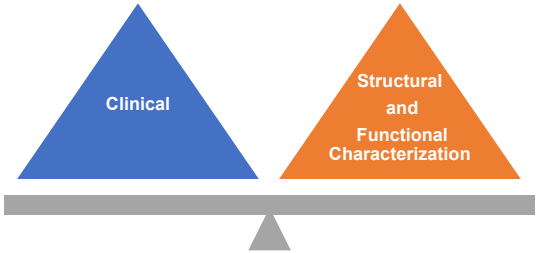
Progression of Biosimilar Approvals

	Zarxio	Inflectra	Erelzi	Amjevita
Name	• Filgrastim-sndz (place holder) • Proposed name: filgrastim-bflm	• Infliximab-dyyb	• Etanercept-szzs	• Adalimumab-atto
Indications studied	• Myelosuppressive chemotherapy	• Rheumatoid arthritis • Ankylosing spondylitis	• Plaque psoriasis	• Rheumatoid arthritis • Plaque psoriasis
Indication coverage	• All non-orphan indications	• All non-orphan indications	• All indications* • No weight-based dosing for children <63 kg (product only available in prefilled syringe)	• All non-orphan indications

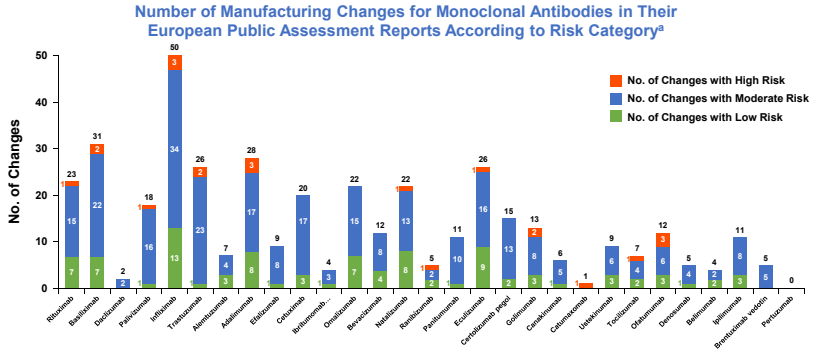
***Since approval, Sandoz has requested removal of psoriatic arthritis and plaque psoriasis indication from label to avoid patent infringement.**

US FDA [website]. https://wayback.archiveit.org/7993/20170404153112/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM436387.pdf. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisAdvisoryCommittee/UCM484859.pdf. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisAdvisoryCommittee/UCM510493.pdf. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisAdvisoryCommittee/UCM510293.pdf. Accessed February 5, 2018. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/761042Orig1s001ltr.pdf. Accessed April 6, 2018.

Biosimilar Balancing Act



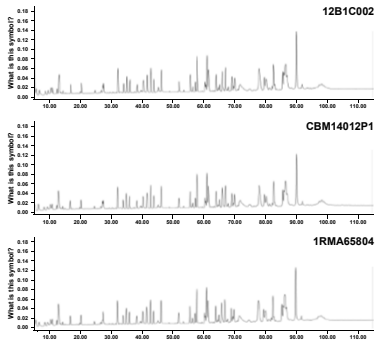
Originator Biologic Manufacturing Changes



[a]During the search period, all non-proprietary names relate only to the trade named medicines listed in Table 1.
Vezér B, et al. *Curr Med Res Opin*. 2016;32(5):829-834. Vizient Presentation. August 2017. Confidential Information.

Infliximab-dyyb Analytic Characterization

RP-HPLC Chromatograms from the Tryptic Peptide Structural Characterization of CT-P13, US-licensed Remicade, and EU-approved Remicade



RP-HPLC = reverse phase–high-performance liquid chromatography.
US FDA. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisAdvisoryCommittee/UCM484859.pdf. Accessed February 5, 2018.

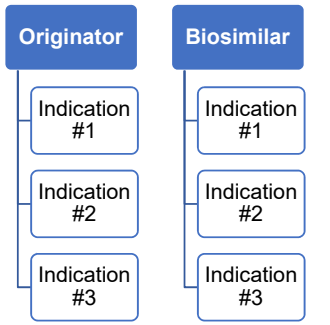
The Efficiency of Bridging

Study (Dates)	Design (Objectives)	Patient Population (Total Number)	Treatment Arms	No. per Arm
CT-P13 3.1 (Global, ex-US) 54 weeks (12/10 to 07/12)	R, DB, PG comparative clinical study: Efficacy, safety, PK, immunogenicity	Moderate to severe RA, MTX-IR N=606	CT-P13 3 mg/kg + MTX EU-approved infliximab	n=302 n=300
CT-P13 1.1 (Global, ex-US) 54 weeks (12/10 to 07/12)	R, DB, PG PK, efficacy, safety, immunogenicity	Moderate to severe AS N=250	CT-P13 5 mg/kg EU-approved infliximab	n=128 n=122
CT-P13 1.4 Single Dose (10/13 to 02/14)	R, DB, PG, SD 3-way PK bridging: PK, safety, immunogenicity	Healthy volunteers N=213	CT-P13 5 mg/kg EU-approved Remicade 5 mg/kg US-licensed Remicade 5 mg/kg	n=71 n=71 n=71

R = randomized; DB = double blind; PG = parallel-group; PK = pharmacokinetics; RA = rheumatoid arthritis; MTX = methotrexate; AS = ankylosing spondylitis; SD = single dose.
www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisAdvisoryCommittee/UCM484859.pdf. Accessed January 20, 2017.

Understanding Extrapolation

Similarity between molecules allows extrapolation

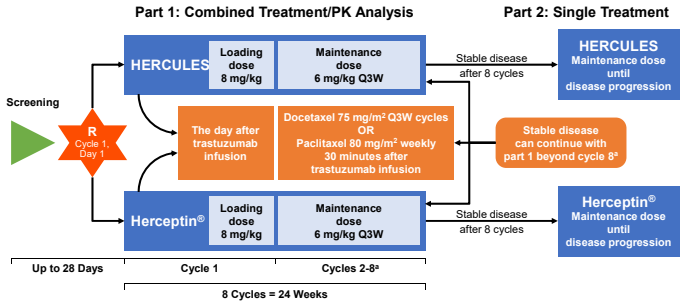


Extrapolation **is not** from one clinical study of the biosimilar to other indications

Extrapolation **is** the scientific justification that a biosimilar can be approved for the same indications as the reference product, even if there are not specific data for each indication of the biosimilar, based upon the totality of evidence of analytic and clinical data

McCamish M, et al. *Clin Pharmacol Ther*. 2015;97(3):215-217.

Clinical Trial Design: Biosimilar Trastuzumab (HER2-positive, Metastatic Breast Cancer)



ªContinue 3-week cycles; if stable disease after 8 cycles, can continue combination treatment on part 1 at investigator's discretion.
HERCULES = Herceptin, Cyclophosphamide, and Epirubicin trial; R = Randomization (within 3 days prior to cycle 1, day 1).
US FDA [website]. https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM566369.pdf. Accessed February 5, 2018.

ORR (Biosimilar vs Originator)

ORR per Central Review at Week 24, ITT1 Population

	MYL-14010 + Taxane (N=230)	EU-Herceptin + Taxane (N=228)
Complete response (CR), n (%)	4 (2)	0
Partial response (PR), n (%)	157 (68)	146 (64)
Stable disease (SD), n (%)	48 (21)	49 (21)
Progressive disease (PD), n (%)	9 (4)	20 (9)
N/A, n (%)	12 (5)	13 (6)
ORR, n (%)	161 (70)	146 (64)
Ratio of ORR (MYL-14010 vs EU-Herceptin)	1.09	
90% CI	(0.98, 1.22)	

ORR ratio = 1.09, well within predefined range of 0.81 to 1.24

ORR = overall response rate; CI = confidence interval.
FDA analysis of data from the Applicant 351(k) BLA submission. US FDA [website]. https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM566369.pdf. Accessed February 5, 2018.

Progression of Biosimilar Approvals

	Mvasi	Ogivri
Name	• bevacizumab-awwb	• trastuzumab-dkst
Indications studied	• Advanced/metastatic non-small cell lung cancer	• Patients with HER-2 positive metastatic breast cancer
Indication coverage	• Metastatic colorectal cancer • Non-squamous non-small cell lung cancer • Glioblastoma • Metastatic renal cell carcinoma • Cervical cancer	• Treatment of HER-2 overexpressing breast cancer • Treatment of HER-2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma
Indications not covered	• Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer that is platinum-resistant or platinum-sensitive (orphan exclusivity)	• None; all orphan exclusivity has expired

Bevacizumab-awwb prescribing information [website]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761028s000lbl.pdf. US FDA [website]. https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM566365.pdf. Bevacizumab prescribing information [website]. https://www.gene.com/download/pdf/avastin_prescribing.pdf. Trastuzumab prescribing information [website]. https://www.gene.com/download/pdf/herceptin_prescribing.pdf. Accessed February 5, 2018.

Biologic Naming, Biosimilar Switching, Substitution, and Interchangeability

What's in a Name?

- **Two names for biologics**
  - Core name (eg, infliximab)
  - Proper name = core name plus 4-letter suffix (eg, infliximab-dyyb)
    - Suffix must be unique and devoid of meaning
  - Will ultimately apply to all biologics
- **Why?**
  - Prevent inadvertent substitution
  - Improve pharmacovigilance
  - Encourage use of FDA-designated suffixes
  - Advance accurate perceptions about biologics

US FDA [website]. www.fda.gov/downloads/drugs/guidances/ucm459987.pdf. Accessed February 5, 2018.

Naming in Practice

Current	Proposed
Filgrastim	Filgrastim-jcwp
Filgrastim-sndz	Filgrastim-bflm
Tbo-filgrastim	Filgrastim-vkzt
Epoetin alfa	Epoetin alfa-cgkn
Infliximab	Infliximab-hjmt
Pegfilgrastim	Pegfilgrastim-ljfd

- No timeline for implementation of proposed proper names for existing products
- However, have seen application to novel biologics (eg, Helimbra® – emicizumab-kxwh)

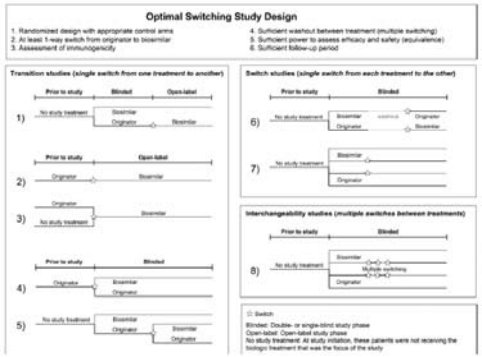
US FDA [website]. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf; Emicizumab-kxwh prescribing information [website]. https://www.gene.com/download/pdf/hemlibra_prescribing.pdf. Accessed February 5, 2018. US FDA. Designation of official names and proper names for certain biological products. August 25, 2015. https://www.fdanews.com/ext/resources/files/08-15/08-28-15-proposedrule.pdf?1520688960. Accessed April 3, 2018.

FDA Draft Guidance for Interchangeability

- Interchangeability: The biosimilar product is expected to produce the same clinical result as the reference product in any given patient
- Biosimilar sponsors should consult with FDA early on to discuss their plans to demonstrate interchangeability
- Sponsors should consider an array of factors when determining the type and amount of data to support a demonstration of interchangeability
  - Product complexity
  - Product-specific immunogenicity risk
- Sponsors should consider the "totality of factors" for their product to determine the amount and type of data that will be required to demonstrate interchangeability

Regulatory Affairs Professionals Society (RAPS) [website]. FDA issues long-awaited biosimilar interchangeability guidance. Michael Mezher. January 17, 2017. https://www.raps.org/regulatory-focus™/news-articles/2017/1/fda-issues-long-awaited-biosimilar-interchangeability-guidance. Accessed April 2, 2018.

Biosimilar Switching and Switch Trial Design



Moots R, et al. *Curr Rheumatol Rep*. 2017;19(6):37.

Biosimilar Equivalence and Switching

- **The ABP 980 Phase 3 LILAC study**
  - Evaluated the safety and efficacy of the trastuzumab biosimilar ABP 980 compared to the reference product in patients with HER-2-positive breast cancer
  - Primary endpoints: Risk difference (RD) and risk ratio (RR) of pathologic complete response in breast tissue and axillary lymph nodes (equivalence margins: +/-13% for RD, 0.759-1.318 for RR)
  - Local review found 48% (ABP 980) and 40.5% (trastuzumab) of patients achieved pathologic complete response
  - RD and RR of pathologic complete response were 7.3% (90% CI: 1.2, 13.4) and 1.19 (90% CI: 1.033, 1.366), respectively
- **Comparison of Switching from the Originator Rituximab (RTX) to the Biosimilar Rituximab GP2013 or Retreatment with the Originator RTX**
  - Safety and immunogenicity of the switch from RTX to GP2013 compared with continued RTX in patients with active RA
  - Patients randomized (1:1) to receive 1000 mg of GP2013 (switch group, n=53) or continue RTX (control group, n=54) for 24 weeks
  - Majority of patients completed the study; incidence of hypersensitivity, infusion-related reactions, and other adverse events were low and similar in both groups
  - Safety profile of patients who switched from RTX to GP2013 was comparable with the patients who received continued treatment with RTX

Von Minckwitz G. Presented at: European Society for Medical Oncology (ESMO) 2017 Congress; September 9, 2017; Madrid, Spain. Abstract 151PD. Tony HP, et al. Presented at: The 2017 ACR/ARHP Annual Meeting; November 7, 2017; San Diego, California. Abstract 2795.

State-Level Biosimilar Substitution Legislation Continues

- **In the past 5 years, 48 states have considered legislation**
- **38 states, plus Puerto Rico, have enacted laws**
- **Common features**
  - FDA determination as interchangeable – "Purple Book"
  - Physician dispense as written authority
  - Physician notification, patient notification, and consent of substitution
  - Record-keeping requirements
  - Cost information to the patient
  - Immunity in some states for pharmacists who make a substitution in compliance with biologics state law

National Conference of State Legislatures [website]. http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx. Accessed April 2, 2018.

Change in Mindset

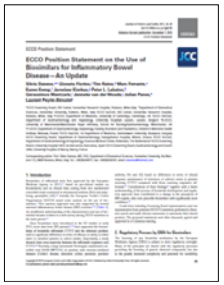
European Crohn's and Colitis Foundation Position Statement (2013)

- "Different biological and biosimilar medicines targeting the same molecule are neither identical in efficacy nor toxicity, even in the same clinical entity."
- "A biosimilar proven effective and safe for one indication may not necessarily be effective and safe for a second indication for which the reference biological has been shown to be safe and effective."
- "Specific evidence obtained in patients with IBD should be required to establish efficacy and safety for this specific indication, because experience with currently licensed biological medicines has already shown that clinical efficacy in IBD cannot be predicted by effectiveness in other indications, such as rheumatoid arthritis."
- "Any decision to substitute a product should only be made with the prescribing health care provider's specific approval and patient knowledge."

Danese S, et al. *J Crohns Colitis.* 2013;7(7):586-589.

European Crohn's and Colitis Foundation Position Statement (2017)

- "Biosimilarity is more sensitively characterized by performing suitable in vitro assays than clinical studies."
- "Clinical studies of equivalence in the most sensitive indication can provide the basis for extrapolation. Therefore data for the use of biosimilars in IBD can be extrapolated from another sensitive indication."
- "When a biosimilar product is registered in the EU, it is considered to be as efficacious as the reference product when used in accordance with the information provided in the Summary of Product Characteristics."
- "Switching from the originator to a biosimilar in patients with IBD is acceptable. Studies of switching can provide valuable evidence for safety and efficacy. Scientific and clinical evidence is lacking regarding reverse switching, multiple switching, and cross-switching among biosimilars in IBD patients."



Danese S, et al. *J Crohns Colitis.* 2017;11(1):26-34.

Not All Mindsets Have Changed

- "Generally, FDA approval of a biosimilar product is an indication that safety and efficacy are not meaningfully different from the reference product."
  - **Not just a general assertion; it IS the definition of a biosimilar**
- "The FDA approval process for biosimilars makes it less likely that large, phase III trials will be undertaken for all approved indications of the reference product."
  - **Not just less likely; it is guaranteed NOT to occur**

Lyman GH, et al. *J Clin Oncol.* 2018 Apr 20;36(12):1260-1265.

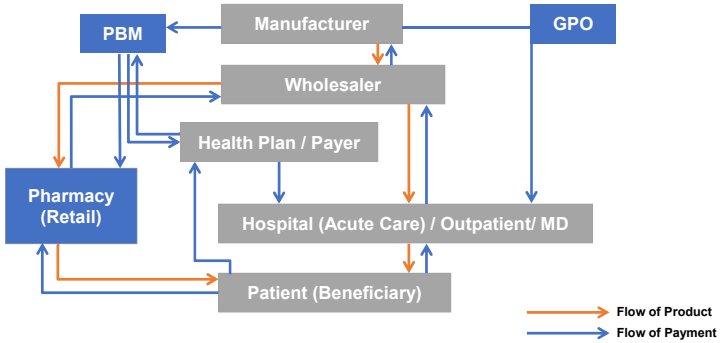
Understanding Biosimilar Value and Other Impossible Tasks

Medicare Part B

- **Prior to January 1, 2018**
- Biosimilars had unique HCPCS code from originator
  - Filgrastim (biosimilar) = Q5101; infliximab (biosimilar) = Q5102
- However, biosimilars of the same originator shared HCPCS codes
  - 100% of biosimilar ASP x 6% ASP[a] of the originator
  - Must use 2-digit identifier to distinguish which biosimilar used
  - ZA = Novartis/Sandoz, ZB = Pfizer/Hospira, ZC = Merck/Samsung Bioepis
- **After January 1, 2018**
  - All biosimilars will be assigned unique HCPCS codes
  - All biosimilars are now eligible for "pass-through" payment; impact for 340B Disproportionate Share Hospitals

[a]4.3% due to sequestration.
HCPCS = Healthcare Common Procedure Coding System; ASP = average sales price.
Centers for Medicare & Medicaid Services [website]. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Part-B-Biosimilar-Biological-Product-Payment.html. Accessed February 5, 2018.

The Dimensions of Payment (Medical and Pharmacy)



PBM = pharmacy benefit manager; GPO = group purchasing organization.
Academy of Managed Care Pharmacy (AMCP) Guide to Pharmaceutical Payment Methods. 2013 Update. Alexandria, VA: AMCP; 2013.

What Savings Have We Seen?

Filgrastim-sndz
- 15% initial discount (WAC)

Tbo-filgrastim
- 19% discount (WAC)

Infliximab-dyyb
- 15% of originator infliximab WAC

Infliximab-abda
- 35% of originator infliximab WAC

WAC = wholesale acquisition cost.
Modern Healthcare [website]. http://www.modernhealthcare.com/article/20160323/NEWS/160319919. DrugCodeLookUp [website]. www.drugcodelookup.com. Big Molecule Watch [website]. http://www.bigmoleculewatch.com/2017/07/24/samsung-bioepis-and-merck-co-launch-renflexis-a-lower-priced-competitor-to-inflectra. Accessed February 5, 2018.

Are Coverage Levels Improving?

Example (filgrastim-sndz)
- Cigna (Medical/Pharmacy) – 1 of 2 preferred
- CVS/Caremark (Medical/Pharmacy) – Exclusive
- ESI (Pharmacy) – 1 of 2 preferred
- Humana (Medical/Pharmacy) – 1 of 2 preferred
- Magellan (Medical) – Exclusive
- OptumRx (Pharmacy) – 1 of 3 preferred
- Prime Therapeutics (Pharmacy) – 1 of 2 preferred
- United (Pharmacy) – Exclusive

Data on file. Sandoz.

Preparing for the Future

Integrating Biosimilars into Clinical Plans

- Educate physicians and other healthcare providers, payers, and patients about biosimilars to:
  - Facilitate informed decision making
  - Promote acceptance of biosimilars into clinical practice
  - Increase accessibility
  - Expedite associated health and economic benefits
  - Increase their confidence
- Be aware of the nocebo effect (ie, the negative equivalent to the placebo effect)
  - Patients switched to/prescribed biosimilars (or even generics) have greater discontinuation rates due to perceived lack of efficacy and adverse effects
  - Providers can unintentionally influence patient perceptions and give patients a negative perception of biosimilars through choice of words and any perceived lack of confidence
- Discuss the importance of shared decision making

Rezk MR, et al. *Rheumatol Ther.* 2017;4:209-218. Jorgensen TS, et al. 2017 ACR/ARHP Annual Meeting. *Arthritis Rheumatol.* 2017;69(suppl10): Abstract 2260. Bridges SL, et al. *Arthritis Rheumatol.* 2018 Mar;70(3):334-344.

Elements of a Formulary Review Document (Biosimilar Perspective)

- **Brand and generic names and synonyms**
- FDA approval information
- Pharmacology and mechanism of action
- FDA-approved indications
- Potential non–FDA-approved indications
- **Dosage form and storage**
- Recommended dosage regimens
- Pharmacokinetic considerations
- Use in special populations
- Pregnancy category and use during breast-feeding
- Comparisons of the drug's efficacy, safety, **convenience, and costs with those of therapeutic alternatives**
- Clinical trial analysis and critique
- Medication safety assessments and recommendations
  - Adverse drug reactions
  - Drug–drug, drug–food interactions
  - Sound-alike and look-alike issues
- **Financial analysis**

ASHP [website]. https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/gdl-pharmacy-therapeutics-committee-formulary-system.ashx. Accessed February 5, 2018.

Biobetters and Beyond

Existing Agent	Modification
Neulasta® (pegfilgrastim)	• Pegfilgrastim on-body injector (Neulasta® Onpro®)
Rituxan® (rituximab) intravenous injection	• Rituximab subcutaneous • Obinutuzumab
Herceptin (trastuzumab)	• Trastuzumab 150 mg • Pertuzumab • Ado-trastuzumab emtansine
Remicade (infliximab)	• Guselkumab (IL-23 inhibitor for plaque psoriasis)
Humira® (adalimumab)	• ABT-122 (bispecific antibody for TNF/IL-17) • ABT-494 (Janus kinase-1 inhibitor) • ALX-0061 (anti-interleukin-6 receptor) mAb

US FDA [website]. Drugs@FDA: FDA Approved Drug Products. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm. Accessed March 1, 2018.

Summary

- The age of biosimilars has arrived (slowly)
- As we move later into 2018 and especially 2019, the rate of approval and launch of biosimilars should increase
- Failure to achieve meaningful uptake could greatly limit the degree of value biosimilars could bring to the market as incentives for more participants would decrease
- Robust uptake and acceptance would make subsequent adoption of future biosimilars (ie, immunotherapy biologics) less challenging
- Pharmacists must lead the way in addressing potential roadblocks (eg, clinical concerns, economic challenges, costs of conversion) to support appropriate evaluation and use of biosimilars

Questions?