AMCP Webinar Series

Biosimilars Naming: How Managed Care Data Consortiums Will Track Biologics

7 May 2014

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Biosimilars Naming:
FTC Follow-On Biologics Workshop, February 4, 2014

- Lesson 1-Follow-on biologic products are scientifically viable
- Lesson 2-Science is not enough—name is critical
- Lesson 3-Creating a viable generic drug market does not reduce brand-name innovation*
- A successful biosimilars pathway requires broad stakeholder cooperation**
- The states are being asked, in effect, to join in a commercial marketing campaign to disparage biologics and to say there is a problem with pharmacovigilance***
- Shared INN names reduce the chance of provider confusion and facilitate patient access****

*Aaron Kesselheim, Department of Medicine, Bringham and Women's Hospital, Harvard Medical School
**Steven B. Miller, Express Scripts, Inc
***Bruce Leicher, Momenta Pharmaceuticals
****Sumant Ramachandra, Hospira

Impact of Legislative and Regulatory Naming Proposals on Biosimilars Competition

David Gaugh, R.Ph.
Senior Vice President for Sciences and Regulatory Affairs
Generic Pharmaceutical Association

Introduction

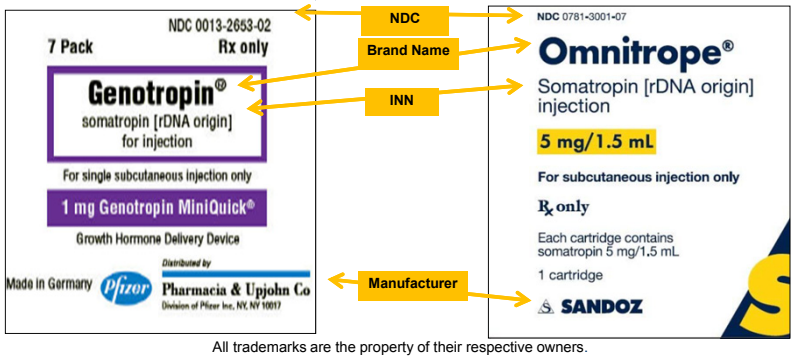
GPhA represents the manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry

Globalization of Naming

- Drugs have two names, the brand name and the International Nonproprietary Name (INN), one or the other/or both are recognized by patients and clinicians who are the key stakeholders in the value of the name
- A global system was established by WHO and administered through various regulatory bodies, to make sure drugs with the same active ingredients had a standard International Nonproprietary Name (INN)
- Naming must be “simple” and “intuitive” to be effective
- Patient safety and accessibility are best ensured when biologic products shares the same “nonproprietary” name with the original biologic

A biologic has several names and identifiers

	Identifies
• Brand Name	Product
• INN	Active substance
• Manufacturer	Company
• National Drug Code (NDC)	Company, product, package
• Lot number	Lot



The INN identifies the active substance (API)

The **INN** is issued by the WHO for;

- Active substance, **NOT product**
- International, **NOT country-specific**
- Non-proprietary, **NOT company-specific**

The **INN** has important roles;

- Allows doctor and other healthcare professionals to identify an active substance regardless of;

  (i) which country(s) they currently practices and

  (ii) which company manufactures the product for that country
- Allows the global exchange of healthcare information

Biologic Naming is a Public Health Issue

Consistent "non-proprietary" naming will;

- ✓ Enable globalization
- ✓ Promote biosimilar intent to drive cost savings
- ✓ Ensure robust market formation
- ✓ Maximize reimbursement and product adoption
- ✓ Support pharmacovigilance systems
- ✓ Reduce confusion of clinicians and patients
- ✓ Build off of a successful foundation of the same INN for both generic and brand name small molecules

- Biosimilar products have been in the European market since 2006/2007 and have had the same **INN**
- The **biosimilar monoclonal antibody** (mAb) products Remsima® and Inflectra® were approved by the **EMA** using the **same INN** as the reference product (*infliximab*)

Key Principles to Product Identification

- GPhA continues to support the same INN
  - Adding more complexity to current naming is NOT recommended as it will neither increase compliance nor reduce confusion
- If needed, GPhA would consider an additional, unattached qualifier;
  - Independent of INN
  - Includes the full company name of the marketing authorization holder
  - On the same line as the INN, but separate/unattached from the INN
    - INN: epoetin alfa
    - Unique Identifier: Epoetin alfa Sandoz
  - Applicable to ALL biologic products, not just biosimilars
  - Applied retroactively
  - Harmonized globally by the WHO INN Program

Pharmacovigilance Issues Related To The Identification of Biologics/Biosimilars

Huifeng Yun, Ph.D.

Assistant Professor – Dept. of Epidemiology, University of Alabama at Birmingham

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Pharmacovigilance issues related to the identification of biologics/biosimilars

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ORIGINAL REPORT

Identifying newly approved medications in Medicare claims data: a case study using tocilizumab

Jeffrey R. Curtis[1]*, Fenglong Xie[1], Rui Chen[2], Lang Chen[1], Meredith L. Kilgore[4], James D. Lewis[2], Huifeng Yun[1,3], Jie Zhang[3], Nicole C. Wright[1] and Elizabeth Delzell[3]

[1] University of Alabama at Birmingham, Division of Clinical Immunology and Rheumatology, Birmingham, AL, USA
[2] Center for Clinical Epidemiology and Biostatistics, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA, USA
[3] University of Alabama at Birmingham, Epidemiology, Birmingham, AL, USA
[4] School of Public Health, University of Alabama at Birmingham, Department of Health Care, Organization and Policy, Birmingham, AL, USA

ABSTRACT

Background After U.S. licensure, parenterally administered medications are identified using non-specific drug codes. Accurately identifying these medications is critical to safety and effectiveness research. Methods to identify medications prior to assignment of specific drug codes have not been well described.

Objectives To describe a generalized approach using non-specific drug codes to identify parenteral therapies in Medicare claims and to assess the ability of that approach to identify tocilizumab (TCZ), a new biologic agent approved in 2010.

Methods We used 2006–2010 Medicare data for a cohort of rheumatoid arthritis patients for algorithm development. Our algorithm classified non-specific drug codes based upon: 1) ICD9 codes; 2) unit values (i.e. dose); 3) codes for infusion/injection procedures; 4) expected versus observed total reimbursement amount and reimbursement per unit. We assessed algorithm performance by linking to an arthritis registry to examine external validity.

Results Of 472 803 claims with non-specific drug codes, 9762 claims satisfied the TCZ algorithm. 74.3% of 9762 claims were classified as TCZ by exact unit price or allowed amount, 4.4% by unique doses, 21.3% by diagnosis code and small deviation from unit price or allowed amount. The algorithm demonstrated good performance characteristics: sensitivity 94% (95% CI 80–99), specificity 100% (99–100) and PPV 97% (84–100).

Conclusion Claims-based algorithms in Medicare or similar data systems can accurately identify newly approved biologics administered parenterally prior to the assignment of specific drug codes. Copyright © 2013 John Wiley & Sons, Ltd.

KEY WORDS—rheumatoid arthritis; Medicare; Part D; biologics; tocilizumab; denosumab; certolizumab; linkage; registry; pharmacoepidemiology

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INTRODUCTION

Accurate identification of medication exposures is essential to validly answer questions related to comparative effectiveness and to conduct pharmacovigilance for new medications. Administrative claims data are commonly used for these purposes because the large sample sizes provide the necessary power to assess both uncommon exposures and rare adverse events. However, these databases suffer from potential misclassification of drug exposures, especially for newly licensed parenteral medications such as biologic therapies when administered by a healthcare provider rather than self-administered by patients. In these circumstances, Medicare providers, for example, obtain reimbursement for medications using Healthcare Common Procedure Coding System (HCPCS) codes. Claims for newly licensed medications use a non-specific HCPCS code (e.g. J3490, J3590) until, and often for some time after, a unique HCPCS code specific to each drug is assigned. These

*Correspondence to: J. R. Curtis, MD MS MPH, 510 20th Street South, Faculty Office Towers 802D, Birmingham, AL 35294, USA. E-mail: jcurtis@uab.edu

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Pharmacovigilance issues related to the identification of biologics/biosimilars

- Administrative claims data could misclassify drug exposures when a newly licensed biologic is administered by a healthcare provider: the provider will typically submit claims containing a HCPCS code that is not specific to the new agent.
- Newly licensed medications may be assigned a non-specific HCPCS code
  - J3490: unclassified drugs
  - J3590: unclassified biologics
- Permanent, specific HCPCS codes are assigned one to two years after a drug comes to market.
- For an agent using one of the non-specific "J" codes, the name, strength of the drug (if applicable) and the actual dosage administered must be indicated on the CMS-1500 form in Block 19 or Block 24 (listed with the procedure code).
- Block 19 data are NOT included in Medicare claims data.

Identifying Biologic Exposures for Newly Licensed Medications

	Tocilizumab	Certolizumab Pegol	Denosumab (for osteoporosis)
Non Specific J code	J3490, J3590, J9999, C9399, Q4082		
Specific J code (date assigned)	J3262 (January 2011) C9264 (July 2010, institutional use only)	J0718 (January 2010) C9249 (April 2009, institutional use only)	J0897 (January 2012) C9272 (October 2010, institutional use only)
Associated diagnosis code sought on claim*	714 (rheumatoid arthritis)	714 (rheumatoid arthritis), 555 (Crohn's disease), 556 (ulcerative colitis), 6960 (psoriatic arthritis), 6961 (psoriasis), 7200 (ankylosing spondylitis)	733 (disorders of bone and cartilage, including osteoporosis)
Unit price** and effective date	3.519/Jan 1, 2010 3.477/Oct 1, 2010	3.417/Jan 1, 2009 3.515/Apr 1, 2009 3.584/Jul 1, 2009 3.800/Oct 1, 2009	14.575/Oct 1, 2010
Unit Count (i.e. dose) Typical Unique from other drugs Possible Unit Count	200,400,600,800 Combination of 200s and 80s(not multiple of 100s) 1, 2, 3, 4…	200,400 N/A 1,2	60 60 1
Infusion code***	96413, 96415	none	none
Injection code***		96372, 96374, 96375	96372, 96374, 96375, 96401
Expected dosing frequency	Every 4 weeks	Every 4 weeks	Every 6 months

Curtis JR, Xie F, et al. PDS 2013

Future Challenges and Potential Solutions

- **Impact on patients, providers, and reimbursement program**
  - Challenge the billing and reimbursement system
  - Physicians send the patients to hospital infusion center
  - Patients purchase medications through Part D coverage
- Potential Solutions to avoid misclassification on newly approved biologics
  - Report NDC codes submitted in Block 19 in Medicare physician file along with J codes
  - Assign specific J codes immediately when infusion drugs approved

Biosimilars Naming: How Managed Care Data Consortiums Will Track Biologics

Bernadette Eichelberger, Pharm.D.
Director, Pharmacy Affairs – AMCP

AMCP Biosimilars Strategy: Connecting Data, Tools and Technology

What we will discuss today

1. AMCP biologic naming position
2. AMCP Biosimilars Collective Intelligence and naming implications
3. Managed Care strategies for accurate identification of biosimilars and innovators

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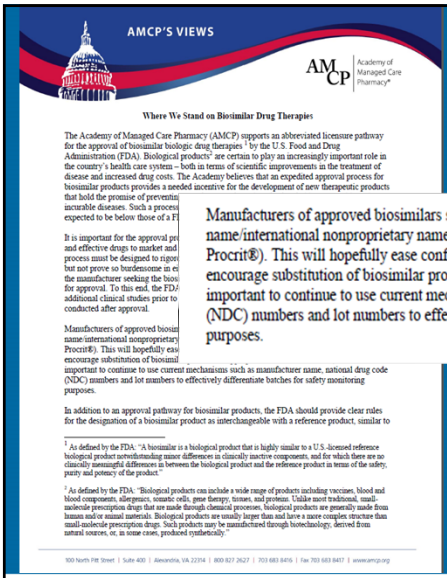
AMCP Position on Biologic Naming


AMCP'S VIEWS

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Where We Stand on Biosimilar Drug Therapies

The Academy of Managed Care Pharmacy (AMCP) supports an abbreviated licensure pathway for the approval of biosimilar biologic drug therapies [1] by the U.S. Food and Drug Administration (FDA). Biological products[2] are certain to play an increasingly important role in the country's health care system – both in terms of scientific improvements in the treatment of disease and increased drug costs. The Academy believes that an expedited approval process for biosimilar products provides a needed incentive for the development of new therapeutic products that hold the promise of preventin incurable diseases. Such a proces expected to be below those of a F

It is important for the approval pr and effective drugs to market and process must be designed to rigor but not prove so burdensome as e the manufacturer seeking the biosi for approval. To this end, the FDA additional clinical studies prior to conducted after approval.

Manufacturers of approved biosim name/international nonproprietary Procrit®). This will hopefully eas encourage substitution of biosimil important to continue to use current mechanisms such as manufacturer name, national drug code (NDC) numbers and lot numbers to effectively differentiate batches for safety monitoring purposes.

In addition to an approval pathway for biosimilar products, the FDA should provide clear rules for the designation of a biosimilar product as interchangeable with a reference product, similar to

[1] As defined by the FDA: "A biosimilar is a biological product that is highly similar to a U.S.-licensed reference biological product notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences in between the biological product and the reference product in terms of the safety, purity and potency of the product."

[2] As defined by the FDA: "Biological products can include a wide range of products including vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and proteins. Unlike most traditional, small-molecule prescription drugs that are made through chemical processes, biological products are generally made from human and/or animal materials. Biological products are usually larger than and have a more complex structure than small-molecule prescription drugs. Such products may be manufactured through biotechnology, derived from natural sources, or, in some cases, produced synthetically."

100 North Pitt Street | Suite 400 | Alexandria, VA 22314 | 800 827 2627 | 703 683 8416 | Fax 703 683 8417 | www.amcp.org

Manufacturers of approved biosimilars should be allowed to use the same government-approved name/international nonproprietary name as the reference product (e.g. epoetin alpha for Procrit®). This will hopefully ease confusion among prescribers and patients and help to encourage substitution of biosimilar products in appropriate instances. However, it is also important to continue to use current mechanisms such as manufacturer name, national drug code (NDC) numbers and lot numbers to effectively differentiate batches for safety monitoring purposes.

EMA: "main drive for an additional code appeared to be added safety, but with many biosimilars now appearing on the market it could be confusing for prescribers as to what a biosimilar actually is, when confronted with multiple qualifiers."

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AMCP Biosimilars Collective Intelligence

- **Our Mission:** Furthering biosimilar adoption by assuring physicians and the public that managed care and industry are working together to monitor biologics using our existing managed care data infrastructure that makes active surveillance in distributed research networks possible
- **Our Strength:** our large managed care databases, and our primary focus on biosimilars and their innovators, and their active and early surveillance.
- **Why AMCP Biosimilars Collective Intelligence?**
  - The task force did not recommend creation of a surveillance system based on the premise that there will be differences in safety between the originator and a biosimilar. It recommended surveillance to counteract the ADR reporting that we frequently see when innovator drugs face a generic or biosimilar challenge.
  - Huge specialty pipeline requires some cost-relief
  - $250B in Biosimilar potential sales (over 10 year) creates opportunities for patients to save $ on copays and biosimilar manufacturers to provide a very important cost-savings

AMCP Biosimilars Collective Intelligence Approach

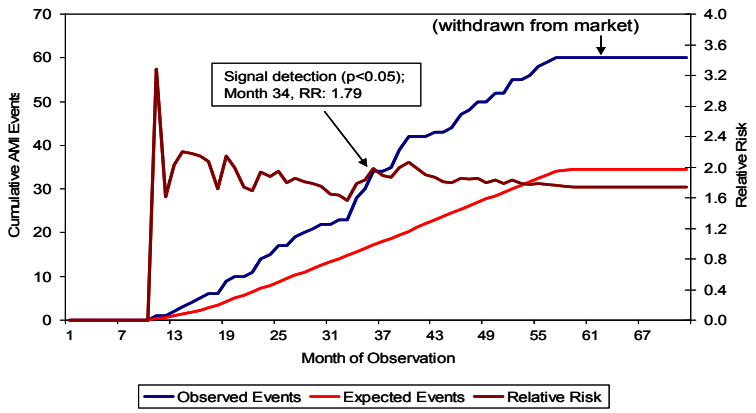
How Will the AMCP Biosimilars Collective Intelligence Work?

- An off-the-shelf approach using proven network tools and technology to provide Active, Early and Focused surveillance
  - Similar operational Distributed Research Networks (DRNs): HMO Research Network, Mini-Sentinel
- Tested machine learning technologies that are able to distinguish Real vs Background noise

AMCP Surveillance: Prospective, Active, Sequential

- Start reviewing data as early as possible. Over time, more observational information is added to the surveillance database.
- Data are extracted, manipulated, summarized, and analyzed *continuously* as more information *accumulates* to search for safety and effectiveness signals.
- Data are being subjected to repeated statistical testing, looking for “signals.”

Observed and expected events for rofecoxib versus naproxen users: 2000-2005



Signal after 28 events (16 expected) among new users of drug

Brown *et al*. (2007) PDS; Adjusted for age, sex, health plan. Outcome: AMI.

AMCP Biosimilars Collective Intelligence Approach

Will AMCP Consortium Look at Innovators *And* Biosimilars?

- Yes
- Biosimilar and Innovator drug data are compared for differences in signals

How Do We Account for Improvements in Pharmacovigilance Since An Innovator Was Launched?

- We will look at historical data but we will *also* begin accumulating data on both the Innovator and Biosimilar as soon as the biosimilar is launched

What Is the Role of the Manufacturer?

- Successful consortiums provide Timely Access, Collaboration, Transparency
- Managed care and industry are aligned on assuring the public and physicians that biologics are being actively monitored
- The AMCP Biosimilars consortium will be overseen by an Advisory Council consisting of key stakeholders, including industry

Mini-Sentinel Partner Organizations

Lead – HPHC Institute

Data and scientific partners

Scientific partners

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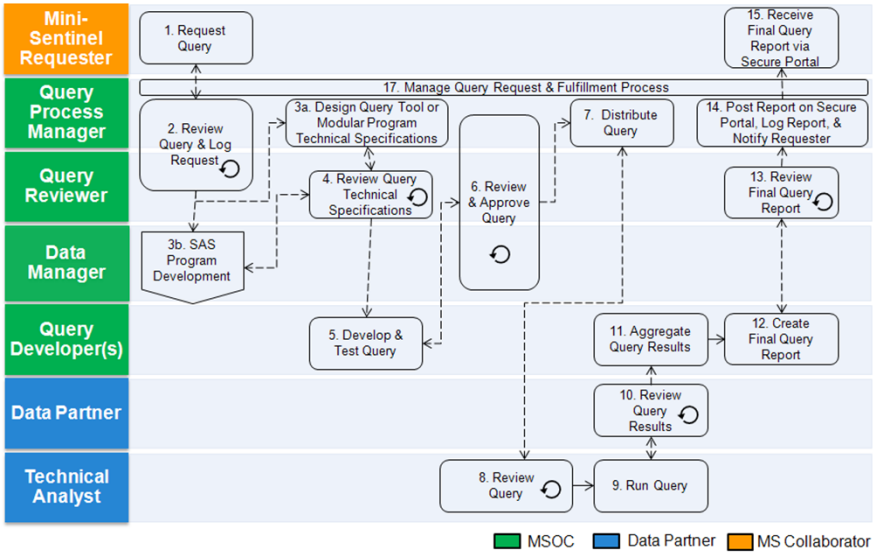
Query fulfillment process



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AMCP Biosimilars Collective Intelligence Project

- **Are Managed Care Organizations Supporting This Initiative?**
  - Our members have devoted significant resources to developing an infrastructure that makes active surveillance possible.
  - At our Task Force meeting on November 12 several large managed care organizations and PBMs indicated their full support for this project and thanked AMCP for the leadership it is providing on this important specialty drug issue

- **Why is AMCP The Ideal Organization To Lead This Surveillance Effort?**
  - AMCP members are aligned on using sound medication management principles and strategies to improve health care.
  - Our members comprise the broad spectrum of specialty drug interests including managed care pharmacists, pharmacoeconomists, researchers, industry, PBMs, specialty pharmacies
  - It is important for managed care pharmacy to marshal its resources for the important public health benefit inherent in monitoring biologic safety and effectiveness, to counteract any nonscientific campaigns that might disparage biosimilars.

AMCP Biosimilars Collective Intelligence Approach

When Will the AMCP Biosimilars Collective Intelligence Be Needed?

- While FDA has not approved final guidance – we are gearing up so that Managed Care Pharmacy is proactive

What Are the Risks of Not Being Proactive?

- Adverse events are attributed to a biosimilar that are "background noise" or false positives
- Members and physicians lose confidence in biosimilars

Why Don't We Let FDA Do the Monitoring?

- FDA will likely be doing some post-approval monitoring and has passive reporting systems in place
- Typically FDA's active surveillance is not proactive—not started as soon as the biologic/biosimilar is available

Managed Care Strategies for Accurate Identification of Biologics

1. Accurate identification of biologics at an ndc level is available to Managed Care Distributed Research Networks. Data warehouses collect ndc on :
   - Outpatient pharmacy claims
   - Specialty pharmacy claims
   - Hospital systems EMRs
   - Outpatient hospital facility EMRs

2. Rapid MCO implementation of the NCPDP Electronic PA standard will facilitate MCO/PBM contributions to the biologic surveillance effort. NCPDP and AMCP will explore expanding the ePA standard to include physician-office transactions.

3. The gap with ndc-level product identifiers is with specialty drugs administered in physician offices. Solutions for this gap:
   - Assign specific J codes immediately when biologics/biosimilars are approved
   - Report NDC codes submitted in HCFA 1500 or UB04 Block 19/24 in addition to J codes
   - Rapid MCO implementation of the NCPDP Electronic PA standard to facilitate MCO/PBM contributions to the biologic surveillance effort.

Managed Care Strategies for Accurate Identification of Biologics

Report NDC on All Physician-Office Drug Claims in Addition to J Codes

- Effective August 1, 2012, physician office administered drugs must include the NDC, quantity and unit of measure on HCFA 1500/UB04 in addition to J codes
- PPACA law now includes all medications dispensed to Medicaid beneficiaries enrolled in Medicaid managed care organizations or to dual eligible, when billed for drug-related HCPCS, CPT and revenue codes
- The NDC submitted must be the actual NDC on the package or container from which the medication was administered.
- In addition, Medicare requires NDC or a “narrative description” in block 19 if an "unlisted procedure code" or a "not otherwise classified" (NOC) code is listed. Medicare will return the claim as “unprocessable” if an "unlisted procedure code" or a NOC code does not have this narrative description
- MCOs are beginning to see some bleed of this process into commercial claims from physician offices
- MCOs are recommending that physician offices supply ndc for all specialty drugs, not just on Medicaid and Medicare claims