Capture of Biologic and Biosimilar Dispensings in a Consortium of U.S.-Based Claims Databases - Utilization of National Drug Codes and HCPCS Modifiers in Medical Claims

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BACKGROUND

- Claims databases are a valuable resource for assessing the utilization, safety, and effectiveness of biologic products
- Challenges in the ascertainment of biologics administered by a healthcare provider from medical claims
  - Typically ascertained using healthcare common procedure coding system (HCPCS) code
  - HCPCS code not immediately assigned for newly licensed infusion biologics
  - Multiple products may share the same HCPCS code
    - J1815 and J1817 for administration of insulin
    - J0885 and Q4081 for administration of Epogen or Procrit
  - Evolving rule on the billing of biosimilars (example in **Table 1**)

Table 1. Billing of infliximab biosimilars administered by a healthcare provider

Biosimilar (Product)	Reference biologic	1/1/2017 to 3/31/2018	4/1/2018 to Present
Inflectra	Infliximab	Q5102 with Modifier ZB	Q5103
Renflexis	Infliximab	Q5102 with Modifier ZC	Q5104

    - 1/1/2016 - 3/31/2018: biosimilars of the same reference biologic assigned the same HCPCS code, with modifiers assigned to identify the manufacturer
    - 4/1/2018 – Present: Unique HCPCS assigned to individual biosimilar
- In recent years, for optimal product identification, the Center for Medicare and Medicaid Services and other insurers have recommended or required the submission of national drug code (NDC) on medical claims
  - This novel data field may improve the identification of the biologics from medical claims
- There are limited data on the use of NDC and HCPCS modifier in medical claims

OBJECTIVES

- To evaluate the utilization of NDC in medical claims
- To understand where and how dispensings of select biologics are documented in claims databases

METHODS

- An observational repeated cross-sectional study
  - Study Period: 1/1/2013 – 9/30/2017
  - Data Source: claims databases of the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) Distributed Research Network (DRN)
  - Study Population: 0-100 years of age with medical and pharmacy coverage for at least one day during the study period
- Exposure of interest consisted of select biologics:
  - Anti-inflammatories
  - Erythropoiesis-stimulating agents (ESAs)
  - Granulocyte colony-stimulating factors (GCSFs)
  - Insulin glargine
  - Biosimilars of Infliximab and Filgrastim
- Data analysis
  - Descriptive analysis
  - Number and proportion of medical claims with at least one NDC
  - Number of dispensings of select biologics, by
    - Type of claims (medical, pharmacy) and code (NDC, HCPCS)
    - Patient characteristics: age, gender, geographic region
    - Encounter-related characteristics: calendar year of encounter, place of service, facility vs. professional
    - Health plan-related characteristics: Medicare, Medicaid, commercial

RESULTS

- Study identified a total of 1,541,969 eligible participants, who contributed 4,053,346 person-years of data
- Of more than 4 million medical claims examined during the study period, 2.3% had an NDC
  - Use of NDC in medical claims increased over time for outpatient, inpatient, and emergency department encounters (**Figure 1**)
- Utilization of NDC in medical claims varied across the biologics examined
  - NDC extensively used in medical claims for infusion anti-inflammatory biologics
    - 54% to 79% of the medical claims had an NDC (Not shown in table or figure)
  - NDC in medical claims identified dispensings of biologics that do not have a product specific HCPCS code
    - 9,792 Lantus dispensings (0.3% of all Lantus dispensings)
    - 2,178 dispensings of vedolizumab; 39% and 28% of vedolizumab dispensings in 2014 and 2015 (**Table 2**)

Table 2. Ascertainment of vedolizumab dispensings

Calendar Year	Total	Pharmacy		Medical					
		NDC		Specific HCPCS		Specific HCPCS+NDC		NOS HCPCS+NDC	
		N	%	N	%	N	%	N	%
2014	706	120	17.00%	289	40.93%	23	3.26%	274	38.81%
2015	6392	954	14.92%	2915	45.60%	723	11.31%	1800	28.16%
2016	14798	1386	9.37%	7962	53.80%	5359	36.21%	91	0.61%
2017	15448	1280	8.29%	7603	49.22%	6552	42.41%	13	0.08%

  - NDC in medical claims allowed 34% of Epogen/Procrit dispensings to be classified as Epogen or Procrit
    - Nearly all (n=527,952, 99%) Epogen dispensings and 70% (n=73,196) Procrit dispensings (**Table 3**)
    - When stratified by calendar year, the proportion of dispensings that cannot be determined to be Epogen or Procrit decreased from 77% in 2013 to 50% in 2017 **(Table 3)**

Table 3. Epogen and Procrit Dispensings identified from Medical Claims

Calendar Year	Epogen or Procrit	Epogen or Procrit (Not assigned)		Epogen		Procrit	
	Total	N	%	N	%	N	%
2013	405525	311357	76.8%	83672	20.63%	10496	2.59%
2014	442228	317093	71.7%	111293	25.17%	13842	3.13%
2015	396550	264430	66.7%	116781	29.45%	15339	3.87%
2016	315542	158965	50.4%	138235	43.81%	18342	5.81%
2017	187936	94787	50.4%	77972	41.49%	15177	8.08%

- Of 26,382 filgrastim biosimilar (Zarxio) dispensings with Q code from medical claims, 51% had a modifier (with or without NDC on the same line), and an additional 12% had an NDC (**Figure 2a**)
- Of 1,244 infliximab biosimilar dispensings with a Q code from medical claims (**Figure 2b**)
  - Inflectra: 462 (38%) dispensings identified using modifier and an additional 3% using NDC
  - Renflexis: <11 dispensings (July 2017 launch)

Figure 1. Proportion of medical claims with at least one NDC over time, by place of service

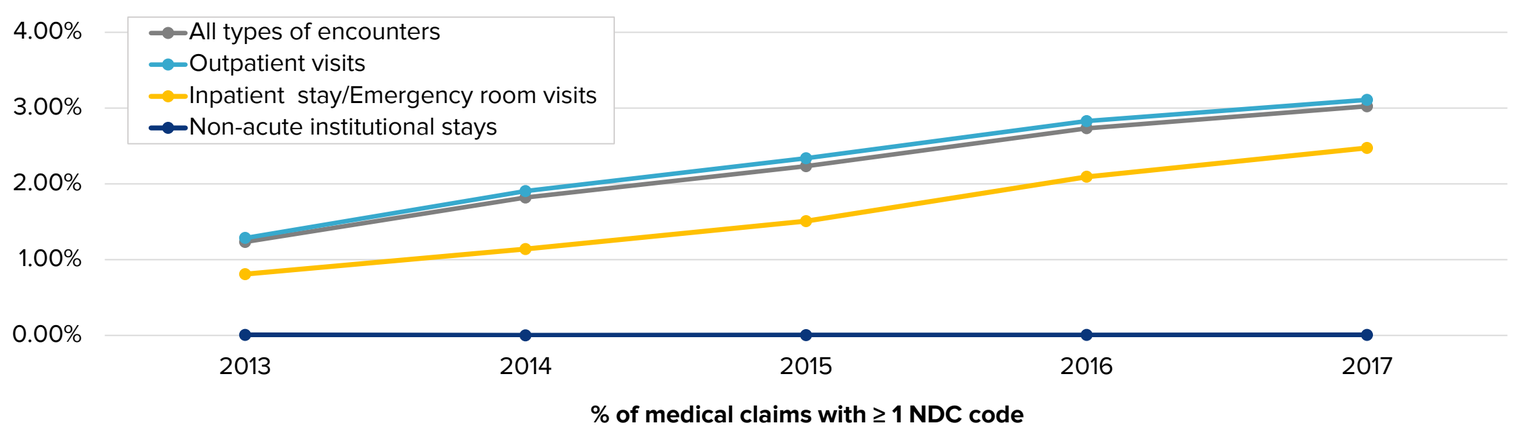


Figure 2a. Filgrastim Bioisimilar Dispensings from pharmacy and medical claims, by source of claim and type of code

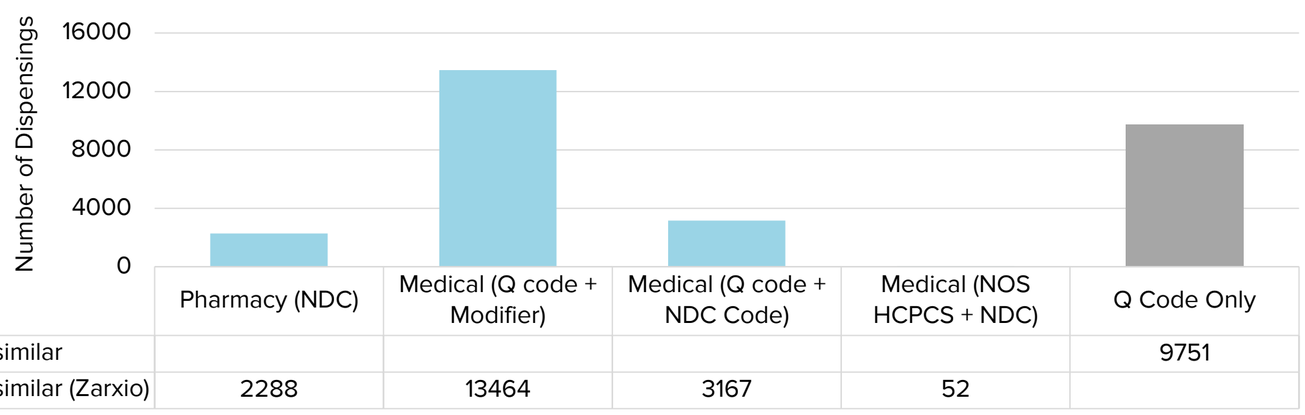
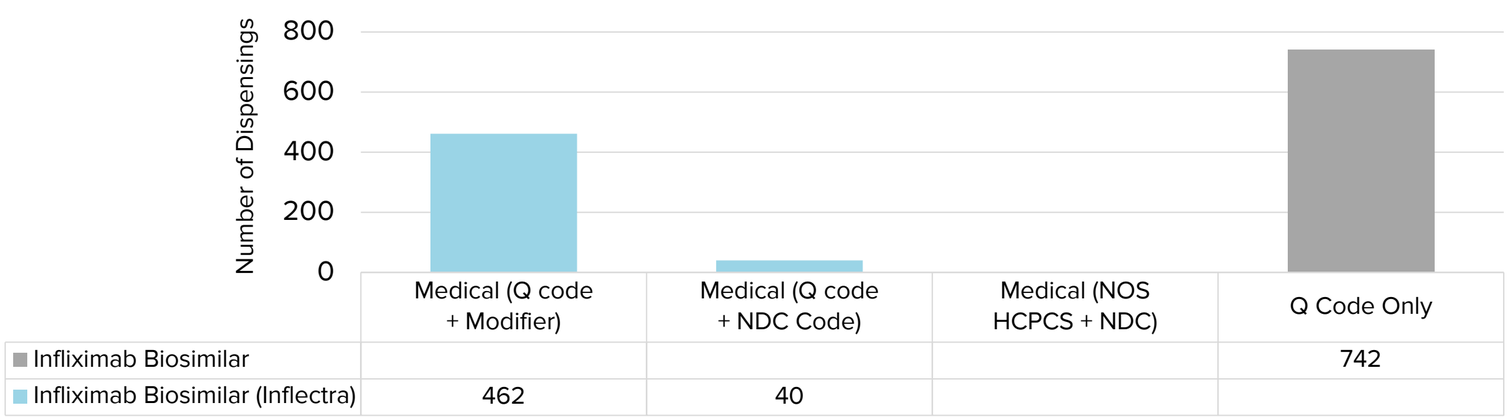


Figure 2b. Infliximab Bioisimilar Dispensings from pharmacy and medical claims, by source of claim and type of code



*The combination of NOS HCPCS code and NDC code from Medical claims identified < 11 dispensings of inflectra; Overall, less than 11 dispensings of Renflexis were identified

CONCLUSIONS

- NDC increasingly used in medical claims
- NDC in medical claims helps to identify recently approved infusion biologics not yet assigned a specific HCPCS code
  - Early dispensings are important for timely pharmacovigeilance research and for characterization of adherence/persistence
- NDC in medical claims helps to identify biologics that do not have a product-specific HCPCS code
  - Only source to identify Lantus, Epogen, or Procrit administered by a healthcare provider
  - Accounts for nearly all Epogen dispensed
- Optimize biosimilar ascertainment
  - Use HCPCS modifier and medical claim NDC if available
  - Of 1,244 dispensings of infliximab biosimilar identified using Q code, 60% did not have a modifier or an NDC
    - Launch of Renflexis may complicate the ascertainment of infliximab biosimilars
- Future studies are warranted to assess impact of incorporating medical claim NDC
  - Study period ended on 9/30/2017; renflexis use not assessed (n<11)
  - Patient-level analysis

ACKNOWLEDGEMENTS

This work was funded through a contract with the BBCIC, a non-profit scientific research consortium. We are grateful for the expertise and insight from Bernadette Eichelberger on the conception and design of the study; for the scientific input and technical assistance from the Work Group members and data partners, including David Cram, Teri DeFor, Pamala Pawloski, D'Angelo Navy, Kyung Lee, Geoffrey Jackson, Nancy Lin, William Yoon, Tiffany Flectcher, and Brian Lehman, and for the project management support provided by Carrie Levin and Sarah Malek.

Poster Presentation at 35th International Conference on Pharmacoepidemiology & Therapeutic Risk Management (ICPE), August 24 - 28, 2019, Philadelphia, PA.