

Study of Granulocyte-Colony Stimulating Factors (G-CSFs) Reference and Biosimilar Products using Real World Data

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PROTOCOL APPROVAL

Study of Granulocyte-Colony Stimulating Factors (G-CSFs) Reference and Biosimilar Products using Real World Data

Protocol Version 1.0

The following individuals have reviewed and approved the final protocol:

BBCIC

Catherine Lockhart, PhD, Pharm.D.

Executive Director

Study Principal Investigator

CVS Health

Cheryl McMahonill-Walraven, PhD

Executive Director

Site Principal Investigator

PearlDiver

Scott Myers, MBA

Director of Research

Study Principal Investigator

HealthPartners

Stephen Asche, MA

Senior Statistician Investigator

Site Principal Investigator

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EXECUTIVE SUMMARY

The following study protocol outlines the goals and procedures of emulating a target trial of course of treatment with G-CSF pegfilgrastim among person with breast cancer.

A biosimilar can be designated as interchangeable if it can be shown that there is no increase in safety risk or loss of efficacy when switching back and forth multiple times between the reference biologic and a biosimilar as compared with staying on the reference biologic. It is very difficult to create clinical trials (CTs) with meaningful endpoints that are sufficiently powerful to examine multiple treatment paths, as such trials require large number of patients to detect the estimated effects. The use of real-world data (RWD) and real-world evidence (RWE) addresses the complexity of building CT switching studies and the lack of participation by certain populations in CTs, which will improve the development of new biosimilars and the regulatory designation of interchangeability. However, the major obstacle to using RWD/RWE in regulatory decision-making about biosimilars is the lack of evidence on the quality of RWD and on the relevance of RWE for these decisions.

The overall goal of this study is to assess RWD sources such as electronic health records and healthcare insurance claims and determine its potential to streamline the premarket and post market regulatory approval process for biosimilars and interchangeable biosimilars. To achieve this goal, we will first establish the availability and completeness of RWD to meet the needs of the FDA regulatory tests for interchangeability. More specifically, the relevant RWD/RWE for a switching study will include switching to a different biologic, discontinuations of treatment, some adverse events, disease stage and activity, and laboratory test results.

We will then emulate a target trial to evaluate the interchangeability of biosimilar drugs as a test case. The switching between pegfilgrastim reference and its biosimilars has been selected as the test case for trial emulation because there are multiple pegfilgrastim biosimilars available in the US, the products are used extensively for febrile neutropenia prophylaxis to chemotherapy administration for multiple cancer diagnoses, and there is no published switching data available. We will emulate a clinical trial using BBCIC observational data to evaluate the interchangeability of pegfilgrastim reference and biosimilar therapies via an examination of safety outcome differences among those who switch between reference and biosimilar therapies and those who do not switch.

This study will advance the development of interchangeable products by providing new information on the quality of RWD and developing new analytical tools for the interchangeability evaluation. These analytical tools will provide generalizable strategies to leverage relevant RWE in regulatory science.

LIST OF ABBREVIATIONS

Abbreviation	Definition
AC-T	Doxorubicin (Adriamycin), cyclophosphamide, paclitaxel
AE	Adverse event
ANC	Absolute neutrophil count
ANA	Antidrug antibodies
ALT	Alanine aminotransferase
AP	Alkaline phosphatase
AST	Aspartate aminotransferase
AT	Doxorubicin, docetaxel
AUC_{0-∞}	Area under the curve from 0 to infinity
BBCIC	Biologics and Biosimilars Collective Intelligence Consortium
BC	Birth control
BM/SCT	Bone marrow or stem cell transplant
BMI	Body mass index;
C_{max}	Maximum concentration
CIN	Chemotherapy-induced Neutropenia
CrCl	Creatinine clearance
DAC	Docetaxel, doxorubicin (Adriamycin), cyclophosphamide
DRN	Distributed Research Network
ECOG	Eastern Cooperative Oncology Group
ESBC	Early-stage breast cancer
ESMO	European Society for Medical Oncology
FDA	The United States Food and Drug Administration
FN	Febrile Neutropenia
G-CSF	Granulocyte-colony stimulating factor
Hgb	Hemoglobin
HIV	Human immunodeficiency virus
ICD-10CM	International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis code
ISPE	International Society for Pharmacoepidemiology
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
k_{el}	Terminal elimination rate constant
NCCN	National Comprehensive Cancer Network
NCI CTCAE	National Cancer Institute Common Toxicity Criteria Adverse Events
PS	Performance status
RT	Radiation therapy
RWD	Real World Data
RWE	Real World Evidence
SCD	Sickle cell disease
SCR	Serum creatinine
SGOT	Serum glutamic oxaloacetic transaminase
SGPT	Serum glutamic pyruvic transaminase
SN	Severe neutropenia
t_{1/2}	Terminal elimination half-life

tmax	Time of maximum serum concentration
TAC	Docetaxel, doxorubicin, cyclophosphamide;
TC	Docetaxel, cyclophosphamide
ULN	Upper limit of normal
Vd/F	Volume of distribution

PROTOCOL REVISION HISTORY

Amendment Version	Date	Protocol Section	Revision Detail and Rationale
1.0	16-May-2024	Complete Protocol	Full version
1.1	17-July-2024	Revised Protocol	Clarifications were added after review

BACKGROUND AND PRIOR RESEARCH

Granulocyte-Colony Stimulating Factor (G-CSF) Prophylaxis for Chemotherapy-induced Neutropenia

Febrile neutropenia (FN) occurs in approximately 25-40% of treatment-naïve patients receiving cytotoxic chemotherapy.^{1,2} FN is associated with prolonged hospitalizations, chemotherapy delays and/or dose reductions, switching to less effective chemotherapy treatments, and death.³⁻⁵ Granulocyte-colony stimulating factor (G-CSF) prophylaxis prevents up to 78% of FN events, enabling delivery of full-dose chemotherapy on schedule.^{2,6} Clinical guidelines recommend prophylactic G-CSF to prevent chemotherapy-induced FN for high (>20%) risk regimens, consideration based on patient factors for intermediate (10%-20%) and low (<10%) FN risk regimens, or for any patient experiencing FN or a dose-limiting neutropenia event.⁷⁻⁹ Pegfilgrastim is a commonly used long-acting G-CSF which is frequently used for primary prophylaxis of FN due to its ease of use with a single dose administration.

The historically high-cost burden associated with pegfilgrastim administration can potentially limit patient access.¹⁰⁻¹⁴ However, G-CSF prophylaxis reduces FN, hospitalizations, and antibiotic use during chemotherapy.^{15,16} Since 2015, several pegfilgrastim biosimilars have been introduced to the US market, increasing biosimilar access and decreasing financial burden on patients and the health care system.^{17,18} A systematic review of clinical trials and cohort studies evaluating efficacy and safety of supportive care biosimilars including G-CSF among cancer patients demonstrated no difference between biosimilars and their reference products, and a recent comparative effectiveness analysis of the pegfilgrastim reference product, and pegfilgrastim-cbqv and pegfilgrastim-jmdb biosimilars for the prevention of FN among patients receiving myelosuppressive chemotherapy across several diagnoses found no difference in FN risk.^{19,20} A 1-year budget impact model conducted among Oncology Care Model participating sites demonstrated that approximately \$3,000 US dollars per patient per year in drug-related costs could be saved by switching from G-CSF originator to biosimilar products.^{21,21} A recent cost-effectiveness analysis compared primary FN prophylaxis with pegfilgrastim and filgrastim for intermediate- and high-FN risk chemotherapy administration demonstrated that pegfilgrastim provided clinical benefits at acceptable costs to both the US payer and the patients.²² Thus, the use of pegfilgrastim biosimilars in this setting have the potential to optimize FN management from a financial perspective. A subsequent analysis of primary and secondary G-CSF prophylaxis among patients with intermediate FN risk from chemotherapy following a diagnosis of breast, lung, and non-Hodgkin lymphoma cancers in three European countries demonstrated primary prophylaxis was cheaper and more effective than secondary prophylaxis for both originator and biosimilar products.^{23,23} Additionally, pegfilgrastim biosimilars had higher incremental cost-effectiveness ratios compared to filgrastim products.²³

Switching between originator and biosimilar products is an expected phenomenon primarily due to drug costs and health care formulary incentives. To date, early literature reviews show biosimilar switching is not related to immunogenicity-related safety concerns or reduced efficacy but there are minimal data surrounding switching analyses across biosimilars and no identified published studies have evaluated pegfilgrastim originator and biosimilar switching.^{24,25} In general, healthcare providers are concerned with multiple originator/biosimilar switches because of the potential consequences to patients, including new adverse events and unintended immune responses.²⁶ But there are differing opinions regarding the process for determining interchangeability.²⁷ Ultimately, providing data on the safety and effectiveness of biosimilar substitution is a critical component to biosimilar uptake and utilization which has the potential to greatly benefit patients.

Breast Cancer Treatment and G-CSF Administration

Chemotherapy for breast cancer is determined by stage, with metastatic disease warranting systemic therapy. The treatment for non-metastatic breast cancer is based on clinical criteria (e.g., lymph node involvement) and operability. Those with earlier stage disease at high risk for recurrence and advanced stage disease usually receive chemotherapy per the clinical practice guidelines.²⁸ Chemotherapy agents commonly employed include anthracyclines and taxanes (e.g., AC-T, DAC) which are associated with high or intermediate FN risk and usually given in conjunction with G-CSF prophylaxis. The use of G-CSF in breast cancer is an established standard of care.

Real World Data (RWD) and the Biosimilar Review Process

Before a biosimilar can be used in place of an originator biologic drug, biosimilar approval by the FDA requires the entity demonstrate high similarity to, with no clinically meaningful differences from, the reference biologic. A designation of interchangeability requires no increase in safety risk or loss of efficacy when switching back and forth multiple times between the reference product and a biosimilar compared with treatment on the reference biologic.²⁹ Additional evidentiary requirements for interchangeability vary based on product or disease characteristics but may include a clinical trial to assess the effect of product switching on meaningful safety and effectiveness outcomes. Comparative efficacy clinical trials assessing the interchangeability of biosimilars with their respective reference products are typically larger, expensive, and require a long duration of time.³⁰ These studies are, in large part, lacking; and partially due to the difficulties associated with the ability to design clinical trials with meaningful endpoints sufficiently powered to examine multiple treatment paths associated with product switching. Such trials require large numbers of patients to detect the estimated effects and the trial complexity, at a potentially large financial expense, is slowing the development and subsequent approval of new interchangeable biologics.

A recent World Health Organization survey identified that one of the challenges with biosimilars are the difficulties with the practice of interchangeability.³¹ This challenge is accompanied by a lack of safety and effectiveness data associated with biosimilar switching.²⁵ To overcome the paucity of switching data currently available and in response to the 21st Century Cures Act call for the FDA to issue guidance on the use of real-world evidence (RWE) in regulatory decision making, this study will assess the potential to use RWD and RWE to improve technical capabilities in regulatory science. Through this study, we will establish the potential of RWD/RWE to streamline the pre-market regulatory approval process for biosimilars and potentially alleviate the need for clinical trials to demonstrate interchangeability.

OBJECTIVES

Research Question

Can RWD/RWE be used to meet the FDA requirements for biosimilar and interchangeable biologic regulatory approval?

Objectives

- (Overall Aim) To assess administrative claims and EHR RWD from the BBCIC's Distributed Research Network (DRN) to generate real world evidence (RWE) to evaluate the

interchangeability of biosimilar drugs traditionally assessed by the Food and Drug Administration (FDA) through the conduct of a randomized or open label clinical trial.

- (Test Case) To emulate a clinical trial using BBCIC observational data to evaluate the interchangeability of G-CSF biologic and biosimilar therapies via an examination of safety outcome differences among those who switch between biologic and biosimilar G-CSF therapies and those who do not switch.³²

STUDY DESIGN

Overall Design

This observational cohort study will be conducted using RWD and existing tools to conduct evaluations based on existing clinical trials of granulocyte-colony stimulating factor (G-CSF) reference and biosimilar products to emulate a switching study to evaluate the interchangeability of the biosimilar and reference products ([Appendix A](#)).³²⁻⁴⁰

Data source

RWD procured from Research Partners (CVS Health/Aetna and HealthPartners) participating in the Biologics and Biosimilars Collective Intelligence Consortium's (BBCIC) Distributed Research Network (DRN) and additional data sources (i.e., PearlDiver).⁴¹⁻⁴⁷

Test Case Overview

We will emulate a hypothetical target trial to evaluate the switching of pegfilgrastim biosimilars with reference pegfilgrastim using available RWD. The design of pegfilgrastim target trial was informed by a previous clinical trial on filgrastim ("Safety and efficacy of alternating treatment with EP2006, a filgrastim biosimilar, and reference filgrastim: a phase III, randomized, double-blind clinical study in the prevention of severe neutropenia in patients with breast cancer receiving myelosuppressive chemotherapy"³²). This study is the only available study evaluating the switching of a G-CSF biosimilar (filgrastim-sndz) with reference filgrastim. To date, no switching studies of pegfilgrastim biosimilars compared to reference pegfilgrastim have been published. We will use the filgrastim switching study to inform the design of our target trial and emulation study, adjusting for differences associated with pegfilgrastim. The elements for the design of a target trial emulation: eligibility criteria, treatment strategies, assignment procedures, follow-up period, outcome(s) of interest, causal contrast(s) of interest, and analysis plan are summarized in [Table 1](#) and will be further described below.

Test case selection justification

Reference and biosimilar pegfilgrastim were chosen for this test case emulation because there are multiple pegfilgrastim biosimilars available in the US, the products are used extensively for FN prophylaxis to chemotherapy administration for multiple cancer diagnoses, and there is no published switching data available. Pegfilgrastim biosimilars were approved by the FDA based on comparisons of extensive structural and functional product characterization, animal data, human PK/PD data, clinical immunogenicity, and other clinical safety and effectiveness data demonstrating that each product is biosimilar to reference pegfilgrastim.

A single diagnosis of breast cancer was chosen to maintain a homogenous and large study population and widespread pegfilgrastim use. Healthcare practitioners are anxious to understand how to operationalize patient care without interchangeability designations, and unclear guidance on substitution. This has implications beyond clinical care, to operational services within cancer treatment centers and dispensing pharmacies to manage consistent patient care.

RESEARCH METHODS

Data Sources

Our population-based, non-interventional retrospective cohort study will employ administrative healthcare claims data from the BBCIC's DRN from one large, national health insurer (CVS Health [Aetna]), an integrated healthcare delivery system (HealthPartners), and an aggregator of commercial, Medicare, and Medicaid claims (PearlDiver). Administrative and available EHR data contributed by research partners to the BBCIC DRN and used for this study are available from 2008 and maintained in the SCDM format.^{41-43,47} This dataset includes 180 million person-years of observations across the three sites. Data variables include patient demographics, clinical diagnoses, medication exposures, and procedures and healthcare utilization.

CVS Health conducts collaborative and non-collaborative observational studies in distributed research networks, such as safety surveillance, chart validations, health outcomes evaluations, and utilization and costs, achieved through retrospective observational descriptive analyses and retrospective and prospective randomized studies. Health care benefit claims data obtained from Aetna, Inc, a national insurance company, a CVS Health company are used to achieve the proposed study objectives. Data includes eligibility, medical and pharmacy claims, and laboratory results since 2008. Aetna's FDA Sentinel Common Data Model (CDM) contains over 37 million commercial and Medicare Advantage patients (as of September 2022) with medical and drug claim experience from January 2008 forward available for research purposes.

HealthPartners Institute is one of the largest medical research centers embedded within a large integrated health care system and encompasses research including neurosciences, critical care, dental and oral health, maternal and child health, chronic disease, cancer, genomics and pharmacogenomics, clinical research, health economics, and mental health. The Institute data are derived from administrative claims and EHR data used to populate the Health Care Systems Research Network Virtual Data Warehouse (VDW) which facilitates collaboration with other research organizations by allowing the pooling and manipulation of common data element and supports the SCDM. HealthPartners data contains EHR data on more than 3 million patients and administrative claims data for >4 million insured lives dating back to 2000.

PearlDiver Technologies is a healthcare research organization offering customizable all-payer claims research services. PearlDiver's Research Platform provides access to fast, accurate research, with over 75 billion longitudinally integrated, HIPAA-compliant patient records amongst over 165 million unique patient lives. These payer types include commercial health plans, government plans such as Medicare and Medicaid, employer-sponsored plans, worker's compensation, and cash payments made by the patient. The PearlDiver Mariner165 Database is an all-payer claims database that includes 75.7 billion claims across 165.7 million patients from January 1, 2010, through October 31, 2022. The PearlDiver Database follows its own data structure, different from the SCDM. Therefore, this study will be able to leverage 3 different RWD structure to emulate the target trial.

Study Population

The observational study include adult patients with a diagnosis of breast cancer as determined by the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes⁴⁸ C50.x, D05.90) and at least 365 days continuous enrollment prior to the Index Date (allowing up to 45-day gaps) including medical and pharmacy coverage. In observational studies on insured populations, such as FDA Sentinel projects, gaps of 45 days or less in health plan enrolment are typically considered administrative gaps (and not lapses in health plan coverage) and ignored. Data will be extracted from the BBCIC DRN database and other sources as described below. The study period will be from 1/1/2016 to 12/31/2023 or latest data available. The first eligible chemotherapy course during the study period will be used for study inclusion. To assure that the qualifying chemotherapy cycle is the first cycle of receipt, we will employ a 180-day “washout period” with no G-CSF or chemotherapy exposure prior to study assignment to avoid unobserved biosimilar use or G-CSF product switches ([Figure 1](#)). The 180-day washout period allows for the majority of delayed claims as well as HER records to be observed, in the pursuit of limiting misclassification bias. Diagnosis of breast cancer will be identified as at least 1 inpatient or outpatient diagnosis claim occurring within the year before the administration of the first chemotherapy regimen. When multiple cancer diagnoses are present, patients will be included if the claim date of breast cancer diagnosis was closest to the start date of cycle 1 chemotherapy. The Index Date is defined as the first exposure to G-CSF therapy associated with cycle 1 chemotherapy administration. Patients who do not receive G-CSF during cycle 1 chemotherapy (but receive G-CSF in later cycles) will not be included in the cohort. G-CSF exposure will be collected for up to 6 cycles of chemotherapy administration.

In the target trial, participants would be randomly assigned to switching arms (only one G-CSF product) and non-switching arms (alternating G-CSF products every cycle). Due to the retrospective design of our observational study, we will not replicate the prospective random assignment of the clinical trial. The G-CSF product utilization following chemotherapy administration will be captured in RWD, and the exposure group will be determined based on their initial G-CSF product in first cycle and subsequent G-CSF products in alter cycles. We will emulate the target trial’s assignment by adjusting for the differences in baseline characteristics between those who switch and those who continue treatment (non-switchers) via stabilized inverse probability of treatment weighting method. The consort diagram for the emulation study is presented in [Figure 2](#).

Inclusion and Exclusion Criteria

Eligibility criteria of the target trial will be informed by previous clinical trials ([Table 2](#)). Patients with a diagnosis of breast cancer who receive cytotoxic chemotherapy ([Appendix C](#)) and initiate G-CSF reference or biosimilars in calendar years 2016-2022 will be included in the study. One year of continuous enrollment prior to G-CSF use with up to 45-day gaps of enrollment allowed. A 180-day lookback period will be utilized to identify prior chemotherapy and G-CSF administration in order to include only treatment-naïve patients.

Patients will be excluded if they have a history myelogenous leukemia, myelodysplastic syndrome, or sickle cell disease, received concurrent or prior radiation therapy within 4 weeks of the Index Date, receipt of prophylactic antibiotics during chemotherapy cycles, receipt of prior chemotherapy or anticancer treatment of breast cancer, or prior G-CSF treatment. Additional exclusions from the analysis of secondary outcomes are: 1) patients who do not receive G-CSF administered after the end of the first chemotherapy cycle, 2) patients who receive non-prophylactic G-CSF (i.e., G-CSF treatment).

Primary comparator groups

This study will compare patients with breast cancer and who have initiated a chemotherapy regimen and prophylactic use of reference pegfilgrastim or a pegfilgrastim biosimilar who 1) initiate therapy with the reference biologic or biosimilar pegfilgrastim therapy and switch to the biosimilar or reference biologic once or more across any chemotherapy cycle (“switchers”) versus 2) patients who initiate the reference or biosimilar therapy but do not switch across any chemotherapy cycle (“non-switcher”). More specifically, patients are classified as switchers as of the first administration date of G-CSF if the prior administration was a reference product and if the current product is a biosimilar or if the prior administration was a biosimilar and current product is a reference product. Additional switching in later cycles is not required to be considered in the switcher group and does not eliminate a patient from the switcher group.

Outcome Measures Definition and Assessment

The primary study outcome is the assessment of the BBCIC’s ability to generate outcomes of interest using administrative data. The assessment would be based on 1) the ability to emulate clinical outcomes, including measures of FN events, TEAEs, data availability, data gaps; and 2) the degree of completeness of clinical outcome measures, including the use of surrogate endpoints to address clinical endpoints that are unavailable in administrative data (e.g., ECOG PS, PK/PD measures). Outcomes and causal contrasts of interest from the target trial, including utilization type outcomes, will be captured according to previous methods.^{49,50} Switching to a different biologic or treatment discontinuations will also be assessed. The incidence of FN requiring health resource utilization (e.g., hospitalization, antibiotic therapy) and treatment emergent adverse events (TEAEs) (e.g., acute respiratory distress syndrome, capillary leak syndrome, cutaneous vasculitis, glomerulonephritis, leukocytosis, serious allergic reaction, splenic rupture, and thrombocytopenia), G-CSF discontinuation, and death due to infection will be captured. Data resources beyond administrative claims will be utilized to capture other common adverse events such as bone pain.

Outcome and exposure measures will be ascertained using J-codes, CPT codes, NDC codes, and ICD-10 CM codes within administrative insurance claims and EHR from individual data partners ([Appendices B, C, D, E](#)).

Primary outcome measures

Primary outcome measures concern the availability of data to conduct a switching study, feasibility metrics, process metrics, transportability metrics, and measures of reliability. The data availability measures will include:

- Availability of treatment-related data elements for building propensity scores to address confounding, including: place of service, dates of chemotherapy cycle initiation, end date of last chemotherapy cycle, number of chemotherapy cycles, type of chemotherapy regimen, chemotherapy risk level for FN, type of G-CSF product received, dates of administration of G-CSF products, reasons for switching between a reference and biosimilar therapy.
- Availability of data to define study endpoints for a switching study, including: outpatient diagnosis of FN, incidence of FN (fever and ANC <.5), incidence of infections, incidence of

hospitalization for FN, lab and/or diagnosis codes for duration of FN and nadir ANC and time to ANC recovery, diagnosis codes for AEs shown in Appendix C.

- Generalizability and transportability metrics across data sources will be reviewed in terms distribution of treatment-related elements among each study population, comparing each switching arms.⁵¹

Test case Outcome Measures

Test case outcome measures concern treatment-emergent adverse events (TEAEs) and clinical outcomes used in the observational study examining the interchangeability of pegfilgrastim reference product with pegfilgrastim biosimilars. TEAEs are commonly measured by NCI CTCAE (National Cancer Institute Common Toxicity Criteria for Adverse Events) in clinical trials. Adverse events will include acute respiratory distress syndrome, capillary leak syndrome, cutaneous vasculitis, glomerulonephritis, leukocytosis, serious allergic reaction, splenic rupture, and thrombocytopenia. Clinical outcomes include patient death, discontinuation of G-CSF, hospitalization for FN, infection diagnosis, and duration of SN. These outcome measures will be analyzed using ICD-10 codes ([Appendix E](#)). ([Appendix E](#)).

. The use of secondary observational data prevents the real-time measure and grading of events. Alternative measures using administrative data could include diagnosis codes and length of hospitalization or outpatient clinical care.

Timing of outcome events

The assessment of most adverse events and secondary outcomes at the level of a chemotherapy cycle begins on the day after initiation of G-CSF administration following chemotherapy completion through one day prior to initiation of the next chemotherapy cycle or for up to 30 days following the G-CSF initiation date if additional chemotherapy is not administered. Serious allergic reaction is assessed from the date of G-CSF administration through 24 hours (day 0).

Assessment of outcomes will also examine the entire time period from the first date of G-CSF administration following chemotherapy completion or on the last date of the chemotherapy through the end date of the sixth or last chemotherapy cycle (whichever is first). Patient data is censored at the end of chemotherapy cycle 6, disenrollment, end of the study data period (whichever happens first).

Data availability and surrogate endpoints

Variables that are not available include measures such as performance status (PS). Alternative PS measure from observational data could include Charleson, Elixhauser, or combined Charlson-Elixhauser score previously used by the BBCIC for other studies.⁴⁶ ICD10 diagnoses present during the 12 months of continuous enrollment prior to study entry will be used to calculate a comorbidity index. Laboratory test results are available at one site and for a subset of patients at a second site. Disease stage and activity may be available in text notes at HP site but would require chart review to obtain.

Exposure Measures Definition and Assessment

Chemotherapy regimens will be ascertained based on all chemotherapy claims within 5 days after the chemotherapy start date. Regimens will be categorized into low (<10%), intermediate (10-20%), high risk (>20%) for FN. Patients with all risk levels for FN will be retained for assessment of primary endpoints for

the test case. Only patients with intermediate and high risk for FN will be included in the assessment of secondary endpoints. Patients having non-prophylactic use of G-CSF will not be included in the assessment of secondary endpoints.

G-CSF product utilization will be captured following chemotherapy administration, including utilization meeting pre-defined criteria for prophylaxis. G-CSF administration defined as treatment for febrile neutropenia will be excluded. The day 0 index date is defined as the start date of first use of G-CSF, which can occur on the last date of chemotherapy through 4 days after chemotherapy cycle end date. Our prior work assessed G-CSF administrations received within 7 days before to 7 days after the chemotherapy start date for pharmacy dispensings and within 7 days after chemotherapy start date for medical procedures.⁴⁷ We also required that G-CSF receipt occurred prior to start of the next chemotherapy cycle.

Patients are classified as switchers as of the first administration date of G-CSF if the prior administration was a reference product and if the current product is a biosimilar or if the prior administration was a biosimilar and current product is a reference product. Additional switching in later cycles is not required to be considered in the switcher group and does not eliminate a patient from the switcher group. Non-switchers are defined as only using a reference product or a biosimilar following all chemotherapy cycles.

Data Collection and Assembly

Patient-level data will be extracted from participating data research partners using previously developed algorithms and methods.⁴⁷ Patient cohorts will be assembled from the data sources described above. Longitudinal healthcare encounter and clinical data meeting the inclusion and exclusion criteria developed previously, and adapted to the target trial requirements will inform this step. Site-specific approval for patient-level data capture will be collected from participating sites.

Data Management

All the Research Partners to maintain physical and operational control of their data while allowing use of the data to meet the study needs. Each system will meet all required State and Federal security guidelines for health data (e.g., Federal Information Security Management Act/FISMA, Health Insurance Portability and Accountability Act of 1996/HIPAA), specifically FISMA compliant for FISMA Moderate Risk security controls as specified in the National Institute of Standards and Technology (NIST) Special Publication 800-53.

We will use the following process to conduct analyses and assemble the data:

- 1) Following protocol approval, data specifications will be developed at each research partner site, tested, and revised as needed.
- 2) Data not currently available through standard SCDM tools (i.e., chemotherapy regimens and consecutive chemotherapy administration cycles) will require de novo programming. All de novo programming will be developed and implemented by Research Partners. De novo programs will be tested and revised as needed.
- 3) Final analytic table will be created by BBCIC collecting results from each Research Partner.

Protection of Human Subjects

Institutional Review Board (IRB) review will be conducted by BBCIC to determine whether this study meets the definition of human subjects research. It is believed that this study does not meet the definition of human subjects research because the Sentinel database from which the BBCIC DRN is extracted was determined by the Office of Human Research Protections to be exempt from Human Subjects Research. Further, the data used for this study will be de-identified at the Research Partner site. Participating Research Partners will be asked to cede authority to the BBCIC IRB or obtain independent IRB review.

Data Quality

BBCIC uses the same data quality assurance procedures as the FDA for the SCDM which includes compliance with “Guidance for Industry and FDA Staff: Best Practices for Conducting and Reporting Pharmacoeconomic Safety Studies Using Electronic Healthcare Data”.⁵²

Two Research Partners (HealthPartners and CVS Health/Aetna) transform local source data into the Sentinel Common Data Model (SCDM) format to be included in the Sentinel Distributed Database (SDD). The QA activities are conducted to assess whether the SDD meets reasonable standards for data transformation consistency and quality, including reviewing data integrity across data tables as well as characterizing data trends and patterns. QA activities are conducted using distributed code to query the content of SCDM formatted tables to determine whether the data conform to SCDM specifications, maintain integrity across variables and across tables, and trend as expected over time. Identified data issues are investigated to determine whether corrective action is required.

Claims within the PearlDiver Mariner dataset are adjudicated. Additionally, claims are regularly subject to audit policies and internal review. Providers supplying claims data are required on an annual basis to contract with qualified independent third parties to conduct defined audits on the validity and reliability of data.

Data Security

Data security processes will be in place to ensure the confidentiality of all systems and data. Every effort will be made to ensure that data are kept secure so that they cannot be accessed by anyone outside the designated study personnel.

Statistical Analysis

Analysis of Primary Outcomes

Analyses will include a description of the patient cohorts according to demographic and clinical characteristics and data sources (CVS Health, HealthPartners, and PearlDiver) ([Table 4](#)). Analysis of primary outcomes (feasibility, process, transportability, reliability metrics) will use frequency counts and percentages for assessing categorical variables and means (SDs, min, max, median, and inter-quartile range) for continuous measures. Missingness rate (number of patients with missing values/number of all patients*100%) will be calculated for each variable. Switching will be visualized with Sankey diagrams.

We will also evaluate mean time to switch or discontinuation, rate of healthcare resource utilization (i.e. number of hospitalizations, emergency room visits, outpatient clinic visits), and describe patient characteristics and relevant outcomes. Discontinuation will be defined as no further observed administration of pegfilgrastim (including reference and all biosimilars) during the study period.

Analysis of Secondary Outcomes

Confounding due to differences in the distribution of demographic and clinical characteristics between the switching group and non-switching group will be addressed via stabilized inverse probability of treatment (sIPT) weighting propensity score method. The predicted probability of switching (i.e., the propensity score) will be estimated via a logistic regression model with baseline characteristics as independent variables including patient age, sex, comorbidity score, year of administration, and chemotherapy FN risk. The distributions of the propensity scores by switching group will be plotted to visualize the degree of overlap between the switching and non-switching groups. The propensity score will be used to compute the sIPT weights that will be applied to the analytic cohorts. Covariate balance will be assessed by using standardized mean differences before and after applying sIPT weights, with standardized difference of the mean (SDM) >0.1 suggestive of important imbalance. A sensitivity analysis will be conducted to reduce the effect of extreme weights. In the sensitivity analysis, propensity scores will be truncated below the 1st and above the 99th percentile of the distribution of all propensity scores. The percentiles for truncation may also be adjusted based on observed distribution.

Rate ratios (RR) of each adverse event and secondary outcomes of interest (including death when available, discontinuation of G-CSF, hospitalization for FN, and infection diagnosis) comparing switching and non-switching groups will be estimated using a generalized estimating equation (GEE) model with Poisson or negative binomial distribution and log link, and a robust variance, weighted by the sIPW.⁵³ Point estimates of RR and 95% confidence intervals will be reported. Adverse events and secondary outcomes will be assessed for non-inferiority in the switcher group compared to the non-switcher group. Non-inferiority margins will be defined as 15%, in line with the target trial.³² Timing of events will be captured using the day of the switch as the index date per cycle, inclusive of the first day, among the switching group. Similarly, the timing of adverse events from the start of each cycle will be captured. For non-switchers, the index date will be the date of G-CSF administration per cycle.

Sensitivity Analysis

To assess the potential impact of observed discontinuation, we will repeat the main analyses and exclude those who discontinued treatment, i.e. no G-CSF treatment was observed in subsequent cycles.

Sample Size

Data extracted during a previous study of the G-CSF utilization and comparisons of filgrastim and pegfilgrastim reference biologics with their respective biosimilars (filgrastim-sndz, pegfilgrastim-jmdb, and pegfilgrastim-cbqv) and tbo-filgrastim identified 2,139 patients who had breast cancer and received trastuzumab from 2020-2022 (**Table 5**). With a longer observation period of 2016-2024, we anticipate doubling the combined study sample size.

Integration of Results from Multiple Data Sources

Data analysis will be performed by research partners at their sites and behind firewalls, and individual-level data will not be available for data integration. Effect estimates from research partners will be summarized using direct meta-analytic techniques with random effects, considering that some heterogeneity will exist across data sources. Forest plots and I^2 will be used to assess the heterogeneity of effect across data sources.

Presentation of Results

Cell counts >0 and <11 will not be shared to protect the anonymity of patients, per standard BBCIC practice. Medication exposures with >0 and <11 incident episodes will be blinded. Institutional Review Board review for the participating Research Partners will be determined by participating research site but previously has been determined to not meet the definition of human subjects research.

Limitations and Potential Solutions

- Sample size: Conclusions may be limited by the number of observations within each switching scenario of interest, especially in cycle-stratified analyses.
- Residual confounding bias: the use of observational data to estimate causal effect is subject to bias that arises from lack of randomization of treatment. Although we will explore explicit target trial emulation design and inverse probability of treatment weighting propensity score method to address observed difference in baseline characteristics between treatment groups, there might be insufficient information on other clinical factors associated with the treatment groups that require adjustment. We will calculate e-values to assess the robustness of our findings to unmeasured confounding.⁵⁴ We expect a large E-value that suggests that our effect estimates are robust to unmeasured confounding. If we find a small E-value suggesting that weak unmeasured confounding could meaningfully reduce the validity of our observed effect estimates, subsequent sensitivity analysis will be conducted. The statistical method for subsequent sensitivity analysis will be guided by the Framework developed by Zhang and colleagues for assessing the impact of unmeasured confounders for credible and reliable RWE and selected based on our evaluation of the nature of the unmeasured confounders and the availability of extra information.
- Incomplete information and misclassification of measurements: Although we will utilize a comprehensive list of codes to identify clinical outcomes and adverse events (Appendix A and D), it is possible to under ascertain the occurrence of outcomes due to incomplete record of healthcare claims, causing measurement misclassification. We will conduct probabilistic sensitivity analyses to quantitatively measure the misclassification bias.

DISSEMINATION OF STUDY RESULTS

Results and interpretation will be delivered in the form of reports and scientific publications, including conference proceedings and manuscripts. Study results will be published following guidelines established by the International Committee of Medical Journal Editors. When reporting results of this study, the appropriate Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist will be followed.

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FIGURES

Figure 1. Target Trial Emulation Study Diagram among Patients Treated with Pegfilgrastim Originator and Biosimilars.

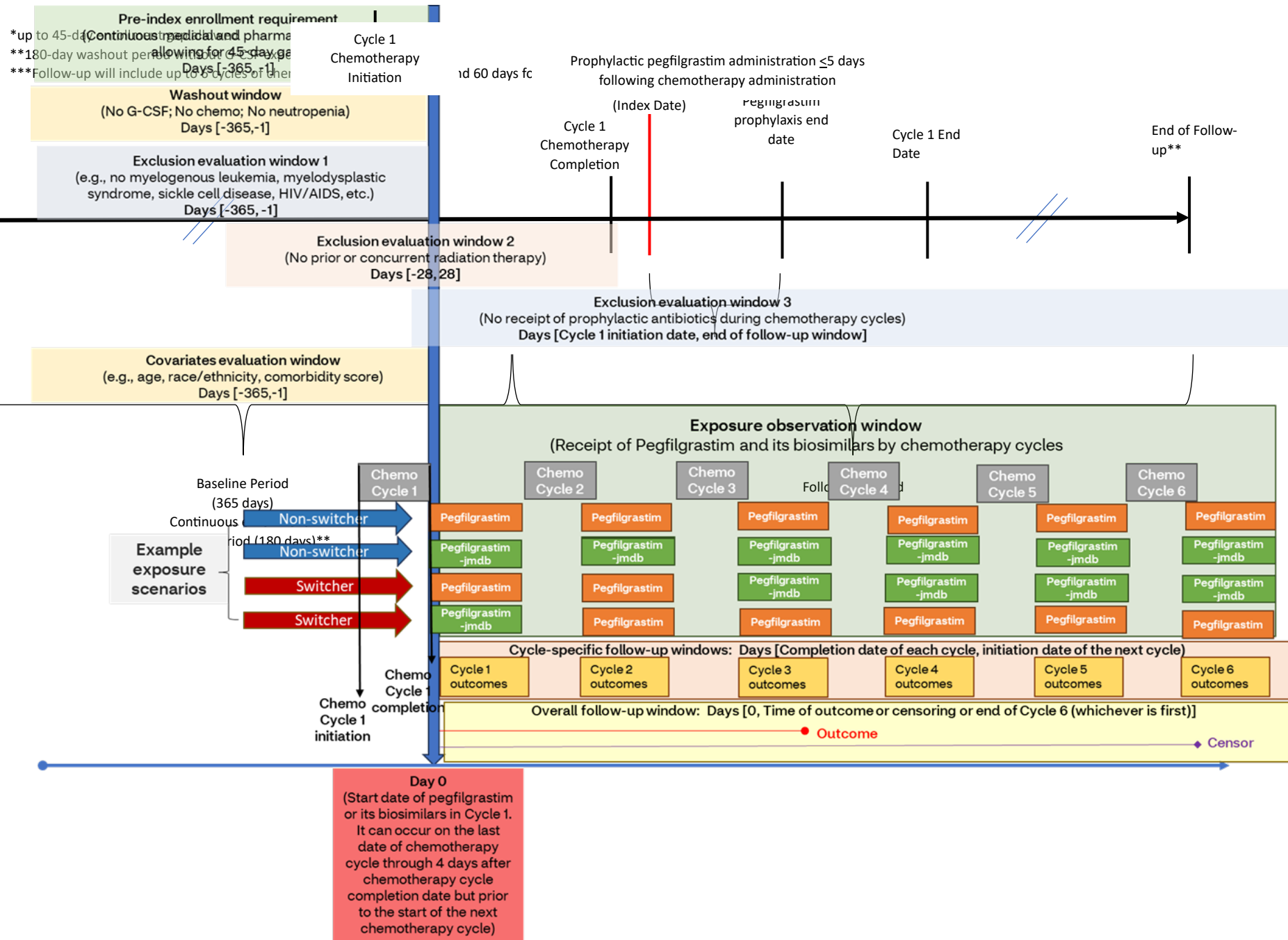
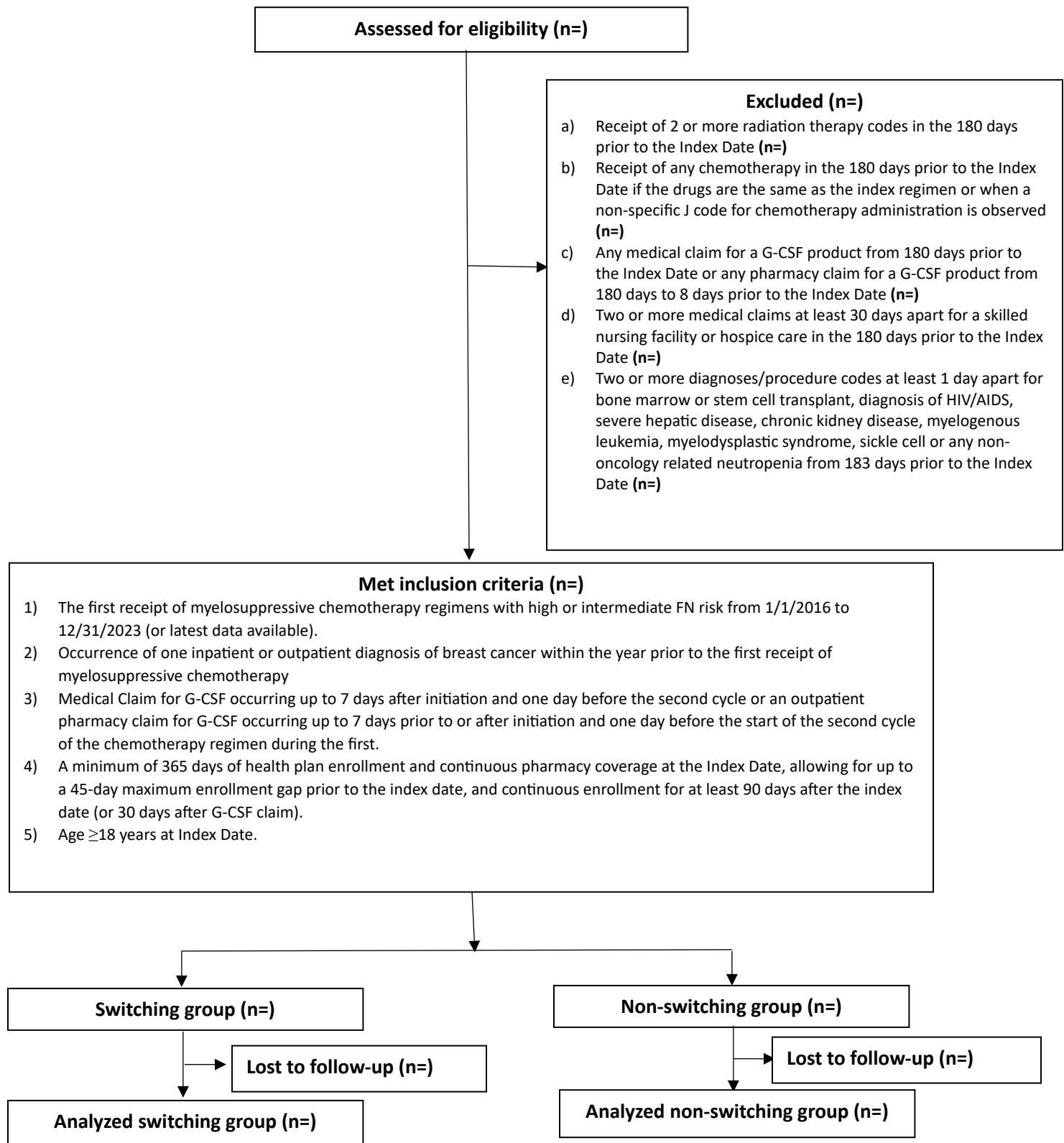


Figure 2. Consort Diagram for the G-CSF Observational Biosimilar Emulation Study.



TABLES

Table 1. Test Case Overview: Design of a Target Trial Emulation Using RWD from BBCIC DRN

	Hypothetical Target Trial (Informed by Blackwell et al., 2018)		Emulation Using RWD from BBCIC DRN
Eligibility Criteria	Inclusion Criteria: • Women aged ≥ 18 years with histologically proven breast cancer • Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2 • Adequate bone marrow function on day 1 of cycle 1 before chemotherapy.	Exclusion Criteria: • See details in Blackwell et al. 2016.	Same.
Treatment Strategy	Two arms (non-switchers) with only one product (biosimilar/reference), and two arms (switchers) with alternating treatments every other cycle (biosimilar then reference or vice versa over six cycles)		Same , except that the subgroups of switchers will be determined by the empirical switch patterns (including the initiation pegfilgrastim, alternating pegfilgrastim, and cycle at pegfilgrastim switch) observed in RWD. The biosimilars of interests are pegfilgrastim-jmdb, pegfilgrastim-cbqv, pegfilgrastim-bmez, pegfilgrastim-apgf, pegfilgrastim-pbbk, pegfilgrastim-fpgk.
Randomized Assignment	Randomized 1:1:1:1 into four arms: no treatment, switched treatment from reference to biosimilar, reference treatment only, and biosimilar treatment only.		Emulation randomization by adjusting for baseline covariates such as patient age, sex, comorbidity score, year of administration, and chemotherapy FN risk, for the 4 groups: reference only, switched from reference to biosimilar, switched from biosimilar to reference, biosimilar only
Follow-up Period	Cycle 2 through cycle 6		Cycle 2 through cycle 6
Outcomes	• incidence of febrile neutropenia (FN) • Incidence of infections • incidence of hospitalizations due to FN		Same. We may examine outcomes informed by previous clinical trials on

	• time and depth of absolute • neutrophil count (ANC) nadir (the patient's lowest ANC in the respective chemotherapy cycle) • time to ANC recovery • Incidence of adverse events (AEs)	pegfilgrastim - See full list of outcomes and data availability in Table 3 and Appendix E .
Causal Contracts of Interest	Intention to treat (ITT) effect	Same , except that the estimates are adjusted for baseline variables via stabilized inverse probability of treatment (sIPT) weighting propensity score method.

Table 2. Common Inclusion and Exclusion Criteria used for Biosimilar Clinical Trials.

Inclusion Criteria	Exclusion Criteria
Adults ≥ 18 years old	Other diagnosis cancer except non melanoma skin cancer or carcinoma in situ of the cervix
Male or female sex	History of myelodysplastic syndrome, or sickle cell disease
Diagnosis of Breast Cancer (no stage requirement)	Prior G-CSF exposure (12 months)
Receipt of G-CSF pegfilgrastim or biosimilar (Appendix A)	Active infection
Receipt of cytotoxic chemotherapy defined in Appendix B)	Receipt anti-infectives
ANC $\geq 1.5 \times 10^9/L$	Prior BM/SCT
Platelet count $\geq 100 \times 10^9/L$	Severe hepatic, renal, GI, cardiac, or cerebral or abnormalities
Hgb > 9 g/dL	Receipt investigational drugs prior 30 days
CrCl > 50 mL/min	Receipt any biologic therapy prior 30 days or during chemotherapy
T Bili ≤ 1.5 mg/dL	Receipt of any device prior 30 days,
AST/SGOT/ALT/SGPT $\leq 2.5 \times ULN$	Receipt radiation therapy prior 30 days
AP $\leq 2.0 \times ULN$	Major surgery prior 30 days
Calculated creatinine clearance > 50 mL/min	Concurrent drug therapy that may interfere with G-CSF therapy (e.g. biosphosphonates)
Total bilirubin ≤ 1.5 mg/dL	
Pregnancy test/birth control	

Table 3. Available Outcome Variables in Observational Data for the Emulation Study at the 3 Research Partner Sites.

Clinical Trial Variable	Available Observational Variables
Incidence and duration of severe (SN) or febrile neutropenia (FN) by and across chemotherapy cycles	Available at 3 sites
Incidence of treatment-emergent adverse events associated with G-CSF	Available at 3 sites
Incidence of hospitalization due to SN/FN	Available at 3 sites
Time and depth of ANC nadir (ANC_{max}, ANC AUC)	ANC available at 2 sites
Time to ANC recovery	ANC available at 2 sites
Number of patients with fever by and across chemotherapy cycles	Available at 1 site
Number of days of fever by and across chemotherapy cycles	Available at 1 site
Frequency of infection by and across chemotherapy cycles	Available at 1 site
Mortality due to infection	Available at 3 sites with limitations
Pharmacokinetic (PK) and pharmacodynamic (PD) measures of G-CSF product(s) C_{max}, AUC, t_{max}, t_{1/2}, k_{el}, Vd/F, safety measured as treatment-emergent adverse events (TEAEs*) by occurrence and severity, and tolerability	Not available at any site
Additional laboratory parameters including CD34+ count, Hgb, SCr, CrCl, AST, ALT, AP,	Available at 2 sites
Vital Signs (Height, weight, BMI, pulse, BP PS**)	Some variables available at 2 sites
Demographics (age, sex, race)	Available at 3 sites
ECG	Potentially available at 2 sites
Immunogenicity (neutralizing antibodies)	Not available at any site
Chemotherapy RDI	Available at 1 site
Hgb=Hemoglobin; SCr=Serum creatinine, CrCl=Creatinine Clearance; AST= Aspartate aminotransferase; ALT= Alanine aminotransferase; AP= Alkaline phosphatase; BMI=Body Mass Index; BP=blood pressure; PS=Performance status; ECG=electrocardiogram; RDI=relative dose intensity *TEAEs measured by NCI CTCAE (National Cancer Institute Common Toxicity Criteria for Adverse Events). Alternative measure in administrative data could include diagnosis codes and would not include grading criteria for severity. **Alternative PS measure from observational data could include Charleson, Elixhauser, or combined Charlson-Elixhauser score.	

Table 4. Chemotherapy Cycle 1 Demographic and Clinical Characteristics of Patients included in the G-CSF Reference and Biosimilar Emulation Study.

Characteristic	N (%)
Age at Index Date (years)	
20-49	
50-64	
65-79	
80+	
Female Sex	
G-CSF Product Receipt	
Pegfilgrastim reference	
Pegfilgrastim-jmdb	
Pegfilgrastim-cbqv	
Pegfilgrastim-bmez	
Pegfilgrastim-apgf	
Pegfilgrastim-pbbk	
Pegfilgrastim-fpgk	
Chemotherapy-associated Febrile Neutropenia Risk	
High	
Intermediate	
Low	
Chemotherapy Regimen Receipt	
Dose-dense AC (doxorubicin, cyclophosphamide) + paclitaxel	
TAC (docetaxel, doxorubicin, cyclophosphamide) / AC (doxorubicin, cyclophosphamide) + docetaxel^	
TC (docetaxel, cyclophosphamide)	
TCH (docetaxel, carboplatin, trastuzumab)	
TCHP (docetaxel, carboplatin, trastuzumab, pertuzumab)	
CMF (cyclophosphamide, methotrexate, fluorouracil)	
FEC (fluorouracil, epirubicin, cyclophosphamide)	
EC (epirubicin, cyclophosphamide)	
Docetaxel	
Paclitaxel	

Table 5. G-CSF Switching by chemotherapy cycle and G-CSF product within HealthPartners and CVS/Aetna.

G-CSF Switch Group	Filgrastim n(%)	tbo-filgrastim n(%)	Filgrastim- sndz n(%)	Pegfilgrastim n(%)	Pegfilgrastim- cbqv n(%)	Pegfilgrastim- jmdb n(%)	Total
G-CSF Cycle1 only	0 (0)	1 (10.00)	2 (8.70)	55 (2.94)	7 (6.54)	7 (6.54)	72
G-CSF in cycle1-2 then DC	0 (0)	0 (0)	4 (17.39)	70 (3.74)	9 (8.41)	6 (5.61)	89
G-CSF in cycle1-3 then DC	1 (4.76)	1 (10.00)	0 (0.00)	98 (5.24)	14 (13.08)	3 (2.80)	117
G-CSF in cycle1-4 then DC	8 (38.10)	1 (10.00)	6 (26.09)	857 (45.80)	45 (42.06)	40 (37.38)	957
G-CSF in cycle1-5 then DC	2 (9.52)	2 (20.00)	1 (4.35)	99 (5.29)	2 (1.87)	5 (4.67)	111
G-CSF in cycle1-6	5 (23.81)	3 (30.00)	3 (13.04)	553 (29.56)	19 (17.76)	17 (15.89)	600
G-CSF switched at any point during Cycles 1-6	5 (23.81)	2 (20.00)	7 (30.43)	139 (7.43)	11 (10.28)	29 (27.10)	193
Total	21	10	23	1871	107	107	2139
DC=discontinuation							

Table 6. Anticipated Emulated Measures in Observational Data at the 3 Research Partner Sites.

Criteria	Emulated Measure when available
Inclusion	
Adults ≥ 18 years old	Age at first index date
Male or female sex	Demographic measure
Diagnosis of Breast Cancer (no stage requirement)	Diagnosis code
Receipt of G-CSF pegfilgrastim or biosimilar	Procedure code, drug dispensing date
Receipt of cytotoxic chemotherapy	Procedure code, drug dispensing date
ANC $\geq 1.5 \times 10^9/L$	LOINC codes, Lab results
Platelet count $\geq 100 \times 10^9/L$	LOINC codes, Lab test results
Hgb > 9 g/dL	LOINC codes, Lab test results
CrCl > 50 mL/min	LOINC codes, Lab test results
T Bili ≤ 1.5 mg/dL	LOINC codes, Lab test results
AST/SGOT/ALT/SGPT $\leq 2.5 \times ULN$	LOINC codes, Lab test results
AP $\leq 2.0 \times ULN$	LOINC codes, lab test results
Calculated creatinine clearance > 50 mL/min	LOINC codes, lab test results , Chronic kidney diagnosis codes
Total bilirubin ≤ 1.5 mg/dL	LOINC codes, lab test results, Liver diagnosis codes
Pregnancy test/birth control	Lab order, LOINC, birth control procedures codes or ndc
Exclusion	
Other diagnosis cancer except non melanoma skin cancer or carcinoma in situ of the cervix	Diagnosis codes
History of myelodysplastic syndrome, or sickle cell disease	Procedure codes
Prior G-CSF exposure (12 months)	Procedure codes
Active infection	Diagnosis code
Receipt anti-infectives	Drug dispensing, ndc codes
Prior BM/SCT	Procedure code
Severe hepatic, renal, GI, cardiac, or cerebral or abnormalities	Diagnosis codes
Receipt investigational drugs prior 30 days	Procedure codes
Receipt any biologic therapy prior 30 days or during chemotherapy	Procedure codes
Receipt of any device prior 30 days,	Procedure codes

Receipt radiation therapy prior 30 days	Procedure codes
Major surgery prior 30 days	Procedure codes
Concurrent drug therapy that may interfere with G-CSF therapy (e.g. bisphosphonates)	Drug dispensing, ndc codes

Dates associated with the inclusion and exclusion criteria will also be collected for assessment with respect to index dates.

APPENDICES

Appendix A. Primary Literature Supporting Pegfilgrastim Biosimilar Product Approval used for Observational Study Emulation.

Clinical Trial	Year	Study Phase	Drug Candidate	Biosimilar Name	Comparators	Inclusion Criteria	Exclusion Criteria	Outcome(s)
Blackwell, K., et al.³²	2018	III	EP2006	filgrastim-sndz	filgrastim-sndz vs reference filgrastim switching	Women ≥ 18 years, ECOG PS ≤ 2 , adequate bone marrow function C1D1 chemotherapy	history myelog leuk, MDS or SCD, concurrent or prior RT within 4 wks of random, prophylactic antibiotics, prior chemo or anticancer treatment of breast cancer, prior G-CSF tx	Incidence FN (oral temp ≥ 38.3 °C and ANC $< 0.5 \times 10^9/L$ on same day), incidence of infections, hosp due to FN, time and depth of ANC nadir, time to ANC recovery, and ANC profile.
Waller, C. F., et al.³³	2018	I	MYL-1401H	pegfilgrastim-jmdb	MYL-1401H vs reference pegfilgrastim	Healthy volunteers 18–65 years of age	History conditions increase risks or affect results (e.g., sickle cell disorders, hematologic malignancies) and history of relevant drug or food allergies, or any previous G-CSF product exposure	Compare PK/PD MYL-1401H with reference pegfilgrastim (pegfilgrastim C_{max} and AUC), safety and tolerability (AEs—NCI CTCAE v4.03), clinical laboratory parameters, vital signs, (ECGs), local tolerability, and

								physical examination; AUC _{0-t} , (t _{max}), (k _{el}), (t _{1/2}), and (V _d /F).
Waller, C. F., et al.³⁴	2019	III	MYL-1401H	pegfilgrastim-jmdb	MYL-1401H vs reference pegfilgrastim	Age ≥ 18 years with newly diagnosed stage II/III breast cancer eligible to receive neoadj or adj TAC chemo; chemo and RT naïve, ECOG PS ≤ 1 and ANC ≥ 1.5 × 10 ⁹	Previous filgrastim product exposure	Duration SN cycle 1 (number days ANC < 0.5 × 10 ⁹ /L). Freq Gr 3 or 4 neutropenia, depth and time to ANC nadir and rate of recovery, and rate of FN*, AEs (NCI CTCAE v4.03).
Glaspy, J. A., et al.³⁵ (abstract only)	2017		CHS-1701	pegfilgrastim-cbqv		Healthy subjects		PK AUC _{0-∞} , C _{max} ; PD maximum absolute neutrophil count (ANC _{max}) and ANC AUC.
Blackwell, K., et al.³⁶	2016	III	LA-EP2006	pegfilgrastim-bmez	LA-EP2006 vs reference pegfilgrastim	Women ≥18 years with ESBC eligible for neoadj or adj TAC chemotherapy, ECOG PS ≥2, ANC ≥ 1.5 × 10 ⁹ /L, platelets ≥100 × 10 ⁹ /L, hgb ≥10 g/dL; T bili WNL, AST/ALT ≤2 × ULN; AP ≤ 3 × ULN; SCr ≤ 1.5 × ULN; negative serum pregnancy test (as applicable) within 7 d randomization	history CML/MDS or presence SCD; prior or current malignancy except noninvasive nonmelanomatous skin cancer, in situ carcinoma of the cervix, or other solid tumor treated curatively and without evidence of recurrence for ≥10 years before enrollment; any RT within 4 weeks of	Mean dur SN during C1 chemo, depth of ANC nadir and time to ANC recovery in cycle 1, number of days of fever, freq of infections by cycle and across cycles, and number episodes of FN by cycle and across cycles.

						and highly effective BC method	randomization; prophylactic antibiotics; prior BM/SCT; previous G-CSF therapy; infection or positive serology for HIV, hepatitis B or C.	
Harbeck, N., et al. ³⁷	2016		LA-EP2006	pegfilgrastim-bmez	LA-EP2006 vs reference pegfilgrastim	Women ≥18 years with breast cancer eligible for adj or neoadj TAC chemo, ECOG PS ≤ 2; ANC ≥1.5 × 10 ⁹ /L, platelets ≥100 × 10 ⁹ /L, Hgb ≥10 g/dL; TBili WNL, AST/ALT ≤2 × ULN; AP ≤3 × ULN; SCr ≤1.5 × ULN negative pregnancy test within 7 days before randomization and effective BC method.	History CML/MDS or SCD; Prior or current malignancy, any significant relevant medical condition, current or prior anti-breast cancer treatment	Duration SN cycle 1 (consecutive days with ANC <0.5 × 10 ⁹ /L – i.e., Gr 4 neutropenia). Depth ANC nadir and time to ANC recovery (days from nadir ANC ≥2 × 10 ⁹ /L) cycle 1; FN incidence (oral temperature of ≥38.3°C with ANC <0.5 × 10 ⁹ /L) or neutropenic sepsis (FN/NS) by cycle and all cycles, number patients with fever (oral temperature ≥38.3°C) for each cycle, number patients with infection by cycle and all cycles, and mortality due to infection.

								Incidence, occurrence/ severity AEs (CTCAE V4.0).
Nakov, R., et al.³⁸	2018	I	LA-EP2006	pegfilgrastim-bmez		Adults 18-45 years; body weight ≥ 60 kg; body mass index 19.0–28.0 kg m ² ; ANC $2-7 \times 10^9$ cells/L; laboratory assessments and haematology parameters WNL; nonsmoker, ex-smoker or smoker who smoked no more than 10 cigarettes/day or equivalent.	Known prior G-CSF; history or presence any clin sig disease (e.g. pulmonary, haematological, hepatic, renal, GI, cardiac, or cerebral or abnormalities; positive test ADA at screening; previous or concurrent malignancy; and abnormal vital signs or abnormal 12-lead electrocardiogram (ECG)	PK/PD/Safety (CTCAE V4.0)
Moosavi, S., et al.³⁹	2020		PF-06881894	pegfilgrastim-apgf		Healthy, non-smoking male or female aged 18–65, BMI of 19–30 kg/m ²	Active systemic or immunologic disease or condition (e.g., Cardiovascular/pulmonary, hepatorenal, systemic infection, lactation), history or current malignancy—except adequately treated squamous or basal cell	PK/PD/immunogenicity/safety

							carcinoma of the skin or cervical carcinoma in situ within 5 years; any disease or condition that might interfere with absorption, distribution, metabolism, or excretion of study drug or increased safety risk	
Kahan, Z., et al. ⁴⁰	2019	III	RBG-02			Chemotherapy-naïve women ≥ 18 - ≤ 65 years with Stage IIb-III breast cancer appropriate for adj/neoadj TC, ECOG PS 0-1, ANC $\geq 1.5 \times 10^9$ /L, platelets $\geq 100 \times 10^9$ /L, and Hgb > 8 g/dL; Est CrCl ≥ 50 mL/min (C-G method), T bili, AST/ALT $< 1.5 \times$ ULN, AP $< 2.5 \times$ ULN. negative pregnancy test and 2 reliable methods of BC	Any other malignancy within 5 years except cervical carcinoma in situ, non-melanoma skin cancer, or superficial bladder tumors (Ta, Tis, or T1) successfully and curatively treated; active infection or systemic anti-infective treatment, RT 4 weeks prior to randomization; past exposure to any G-CSF; concurrent anti-cancer therapy, concomitant treatment with	Mean duration SN (ANC $< 0.5 \times 10^9$ /L) cycle 1. Duration of SN (ANC $< 0.5 \times 10^9$ /L) Cycles 2-4, incidence of SN and FN Cycles 1 and 2, time to ANC recovery and the depth of ANC nadir in Cycles 1 and 2.

							bisphosphonates; prior BM/SCT; history or presence of SCD, and significant cardiovascular disease	
SPI-2012 vs Pegfilgrastim in management of neutropenia in breast cancer patients with docetaxel and cyclophosphamide 2020. NCT02953340, 2020 (no publications to date; results at clinical trials.gov; Results Posted SPI-2012 vs Pegfilgrastim in Management of Neutropenia in Breast Cancer Participants With Docetaxel and Cyclophosphamide ClinicalTrials.gov)	2020	III	SPI-2012 pegfilgrastim		SPI-2012 vs pegfilgrastim	• New ESBC (Stg1-IIIa operable), • Candidate adj or neo-adj TC chemo • ECOG PS ≤ 2 • ANC $\geq 1.5 \times 10^9/L$ • Platelet count $\geq 100 \times 10^9/L$ • Hgb $> 9 \text{ g/dL}$ • Calculated CrCl $> 50 \text{ mL/min}$ • Total bilirubin $\leq 1.5 \text{ mg/dL}$ • AST/SGOT/ALT/S GPT $\leq 2.5 \times \text{ULN}$ • AP $\leq 2.0 \times \text{ULN}$	• Active concurrent malignancy (except non melanoma skin cancer or carcinoma in situ of the cervix) or life-threatening disease • Locally recurrent or metastatic breast cancer • Known sensitivity to E. coli-derived products • Concurrent adj cancer therapy • Previous G-CSF product exposure in 12 months prior to study drug • Active infection, receipt anti-infectives, or underlying condition	Duration of severe neutropenia and time to ANC recovery, depth of ANC nadir, FN events, number neutropenic complications in cycle 1. Duration SN cycles 2-4, RDI chemotherapy

							impairing receipt protocol treatment • Prior BM/SCT • Receipt investigational drugs, any biologics, devices, RT, or major surgery 30 days prior to enrollment	
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TAC = Docetaxel, doxorubicin, cyclophosphamide; ECOG = Eastern Cooperative Oncology Group; PS = Performance Status; TC = docetaxel, cyclophosphamide; ANC – Absolute neutrophil count; SN = severe neutropenia; AEs = Adverse events; NCI CTCAE = National Cancer Institute Common Toxicity Criteria Adverse Events; $AUC_{0-\infty}$ = Area under the curve from 0 to infinity; C_{max} = Maximum concentration; SCR = Serum creatinine; BC = Birth control; SCD = Sickle cell disease; HIV = human immunodeficiency virus; ADA = antidrug antibodies; BMI = Body mass index; AT = doxorubicin, docetaxel; CrCl = Creatinine clearance; t_{max} = time of maximum serum concentration; k_{el} = terminal elimination rate constant; $t_{1/2}$ = terminal elimination half-life; V_d/F = volume of distribution; ESBC = Early-stage breast cancer; Hgb = Hemoglobin; AST = Aspartate aminotransferase; SGOT = Serum glutamic oxaloacetic transaminase; ALT = Alanine aminotransferase; SGPT = Serum glutamic pyruvic transaminase; ULN = Upper limit of normal; AP = Alkaline phosphatase; BM/SCT = Bone marrow or stem cell transplant; RT = Radiation therapy;

*FN defined per European Society for Medical Oncology (ESMO) as $ANC < 0.5 \times 10^9 /L$ or expected to fall below $0.5 \times 10^9 /L$, with a single oral temperature $> 38.5^\circ C$ or 2 consecutive readings $> 38.0^\circ C$ for 2 h.

Appendix B. Administrative codes for outpatient pharmacy dispensings for G-CSF prophylaxis.

Group	J-codes*	CPT Codes**	NDC Codes***
Filgrastim	J1442 JA mod IV JB mod SQ		54569482400, 54868252200, 54868252201, 54868305000, 54868502000, 55513020901, 55513020910, 55513020991, 55513034701, 55513034710, 55513034801, 55513034810, 55513053001, 55513053010, 55513054601, 55513054610, 55513092401, 55513092410, 55513092491
tbo-filgrastim	J1446 J1447		63459091001, 63459091011, 63459091012, 63459091015, 63459091017, 63459091018, 63459091036, 63459091201, 63459091211, 63459091212, 63459091215, 63459091217, 63459091218, 63459091236, 63459091853, 63459091859, 63459092053, 63459092059
Filgrastim-sndz	Q5101		61314030401, 61314030410, 61314031201, 61314031210, 61314031801, 61314031805, 61314031810, 61314032601, 61314032605, 61314032610
Filgrastim-aafi	Q5110		00069029101, 00069029110, 00069029201, 00069029210, 00069029301, 00069029310, 00069029401, 00069029410
Filgrastim-ayow	Q5125		70121156801; 70121156807; 70121156907; 70121157001; 70121157007; 70121157107
Pegfilgrastim prefilled syringe	J2505^ J2506		54868522900; 55513019001; 55513019201
Pegfilgrastim-jmdb	Q5108		67457083306; 83257000541
Pegfilgrastim-cbqv	Q5111		70114010101; 70114012001; 70114013001
Pegfilgrastim-bmez	Q5120		61314086601
Pegfilgrastim-apgf	Q5122		00069032401
Pegfilgrastim-pbbk	Q5130		70121162701
Pegfilgrastim-fpgk	Q1527		65219037110
Pegfilgrastim On-body	J2505 J2506	96377	55513019201
Pegfilgrastim-cbqv autoinjector	Q5111	96377	70114012001
*Healthcare Common Procedure Coding System (HCPCS) J-codes **Current Procedural Terminology (CPT) codes ***National Drug Codes (NDC) ^Discontinued 12/31/2021			

Appendix C. National Comprehensive Cancer Network (NCCN)-designated chemotherapy regimens with high or intermediate febrile neutropenia risk for breast cancer.⁹

Chemotherapy Regimen	NCCN FN risk
Dose-dense AC (doxorubicin, cyclophosphamide) + dose-dense paclitaxel	High
TAC (docetaxel, doxorubicin, cyclophosphamide) / AC (doxorubicin, cyclophosphamide) + docetaxel ^a	High/ intermediate
TC (docetaxel, cyclophosphamide)	High
TCH (docetaxel, carboplatin, trastuzumab)	High
TCHP (docetaxel, carboplatin, trastuzumab, pertuzumab)	High
CMF (cyclophosphamide, methotrexate, fluorouracil)	Intermediate
FEC (fluorouracil, epirubicin, cyclophosphamide)	Intermediate
EC (epirubicin, cyclophosphamide)	Intermediate
Docetaxel	Intermediate
Paclitaxel	Intermediate

Appendix D. NDC codes for outpatient oral antibiotics administered for febrile neutropenia prophylaxis during chemotherapy administration.

BRAND DRUG NAME	GENERIC DRUG NAME	NDC Code
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029607112
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029607212
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029607347
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029607447
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029607527
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029607531
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029608012
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029608027
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029608031
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029608522
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029608523
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029608539
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029608612
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029608621
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029608729
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029608739
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029608751
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029609022
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029609023
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029609039
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029609229
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029609239
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029609251
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029609422
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029609424
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029609425
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029609429
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029609439
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029609440
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029609445
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029609446
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029609451
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029609628
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029609640
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029609648
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00029609660

AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00093227034
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00093227234
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00093227434
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00093227534
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00093227773
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00093227973
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00093867574
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00093867575
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00093867578
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00143924920
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00143985316
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00143985324
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00143985375
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00143998101
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00143998150
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00143998175
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00143998201
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00143998250
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00143998275
AMOX	AMOXICILLIN & POT CLAVULANATE	00172740128
AMOX	AMOXICILLIN & POT CLAVULANATE	00172740228
AMOX	AMOXICILLIN & POT CLAVULANATE	00172740310
AMOX	AMOXICILLIN & POT CLAVULANATE	00172740342
AMOX	AMOXICILLIN & POT CLAVULANATE	00172740410
AMOX	AMOXICILLIN & POT CLAVULANATE	00172740442
AMOX	AMOXICILLIN & POT CLAVULANATE	00172740520
AMOX	AMOXICILLIN & POT CLAVULANATE	00172740521
AMOX	AMOXICILLIN & POT CLAVULANATE	00172740522
AMOX	AMOXICILLIN & POT CLAVULANATE	00172740620
AMOX	AMOXICILLIN & POT CLAVULANATE	00172740621
AMOX	AMOXICILLIN & POT CLAVULANATE	00172740622
AMOX	AMOXICILLIN & POT CLAVULANATE	00172740714
AMOX	AMOXICILLIN & POT CLAVULANATE	00172740722
AMOX	AMOXICILLIN & POT CLAVULANATE	00172740726
AMOX	AMOXICILLIN & POT CLAVULANATE	00172740814
AMOX	AMOXICILLIN & POT CLAVULANATE	00172740822
AMOX	AMOXICILLIN & POT CLAVULANATE	00172740826
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00247002603
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00247002604
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00247002615
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00247002621

AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00247002630
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00247002704
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00247002709
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00247002714
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00247002715
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00247002720
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00247002721
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00247007730
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00378083094
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00378083194
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00378083201
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00378083335
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00378083435
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00378083520
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00378083534
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00378083575
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00378083609
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00378083675
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00403035918
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00403035930
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00403036118
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00403036518
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00403036718
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00403036930
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00403037120
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00403037130
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00403071318
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00403107918
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00403107920
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00403518518
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	00403519318
AMOX	AMOXICILLIN & POT CLAVULANATE	00440710703
AMOX	AMOXICILLIN & POT CLAVULANATE	00440710704
AMOX	AMOXICILLIN & POT CLAVULANATE	00440710730
AMOX	AMOXICILLIN & POT CLAVULANATE	00440710802
AMOX	AMOXICILLIN & POT CLAVULANATE	00440710803
AMOX	AMOXICILLIN & POT CLAVULANATE	00440710804
AMOX	AMOXICILLIN & POT CLAVULANATE	00440710820
AMOX	AMOXICILLIN & POT CLAVULANATE	00440710830
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00781161966
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00781164366

AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00781183120
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00781185220
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00781187431
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00781194339
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00781194382
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00781610246
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00781610446
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00781613948
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00781613954
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	00781613957
AMOX	AMOXICILLIN & POT CLAVULANATE	10544033120
AMOX	AMOXICILLIN & POT CLAVULANATE	10544037020
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	10544095106
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	12280015350
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	12280015375
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	12280015420
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	12280015550
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	12280015615
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	12280015675
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	12280015730
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	12280015800
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	12280015850
AMOX/K	AMOXICILLIN & POT CLAVULANATE	12634080771
AMOX/K	AMOXICILLIN & POT CLAVULANATE	12634080780
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	16590001920
AMOX/K	AMOXICILLIN & POT CLAVULANATE	16590001930
AMOX/K	AMOXICILLIN & POT CLAVULANATE	16590002010
AMOX/K	AMOXICILLIN & POT CLAVULANATE	16590002014
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	16590002020
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	16590002028
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	16590002030
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	16590036940
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	16714001401
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	16714029201
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	16714029202
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	16714029203
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	16714029301
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	16714029302
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	16714029303
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	16714029401
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	16714029402

AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	16714029403
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	16714029501
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	16714029601
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	16714029701
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	16714029702
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	16714047601
AMOX/K	AMOXICILLIN & POT CLAVULANATE	16714047701
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	16714047801
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	16714047802
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	16714049401
AMOX	AMOXICILLIN & POT CLAVULANATE	18837021620
AMOX	AMOXICILLIN & POT CLAVULANATE	18837021630
AMOX/K	AMOXICILLIN & POT CLAVULANATE	18837035720
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	21695021404
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	21695021420
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	21695021520
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	21695021528
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	21695040112
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	21695040120
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	21695054600
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	21695054650
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	21695076700
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	21695076750
AMOX/K	AMOXICILLIN & POT CLAVULANATE	23490008100
AMOX/K	AMOXICILLIN & POT CLAVULANATE	23490008102
AMOX/K	AMOXICILLIN & POT CLAVULANATE	23490008103
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	23490507401
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	23490507402
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	23490507403
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	23490507501
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AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	23490694001
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	23490694002
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	23490694003
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	23490697701
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	23490697900
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	23490697901
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	23490758501
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	23490758502
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	23490758503
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	23490796101

AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	23490796102
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	23490796103
AMOX/K	AMOXICILLIN & POT CLAVULANATE	33261011101
AMOX/K	AMOXICILLIN & POT CLAVULANATE	33261011114
AMOX/K	AMOXICILLIN & POT CLAVULANATE	33261011120
AMOX/K	AMOXICILLIN & POT CLAVULANATE	33261011201
AMOX/K	AMOXICILLIN & POT CLAVULANATE	33261011220
AMOX/K	AMOXICILLIN & POT CLAVULANATE	33261042801
AMOX/K	AMOXICILLIN & POT CLAVULANATE	33261046401
AMOX/K	AMOXICILLIN & POT CLAVULANATE	33261060001
AMOX/K	AMOXICILLIN & POT CLAVULANATE	33261098801
AMOX/K	AMOXICILLIN & POT CLAVULANATE	33261098901
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	33358003020
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	33358003120
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	35356003728
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	35356003740
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	35356018814
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	35356046328
AMOX/K	AMOXICILLIN & POT CLAVULANATE	35356098114
AMOX/K	AMOXICILLIN & POT CLAVULANATE	35356098120
AMOX/K	AMOXICILLIN & POT CLAVULANATE	35356098215
AMOX/K	AMOXICILLIN & POT CLAVULANATE	35356098220
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	40893008103
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	40893008201
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	40893008203
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	40893008315
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	40893008321
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	40893008415
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	40893008421
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	40893008430
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	42254023212
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	42254028200
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	42549053120
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	42549057020
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	42571016030
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	42571016101
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	42571016142
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	42571016201
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	42571016242
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	43063007703
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	43063007704

AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	43063007706
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	43063034203
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	43063037702
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	43598000351
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	43598000354
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	43598000369
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	43598000451
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	43598000452
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	43598000453
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	43598000614
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	43598001251
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	43598001252
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	43598001253
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	43598002028
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	43598002040
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	43598002114
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	43598020351
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	43598020354
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	43598020369
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	43598020451
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	43598020452
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	43598020453
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	43598020614
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	43598020850
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	43598020851
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	43598020852
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	43598021350
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	43598021351
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	43598021352
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	43598021830
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	43598022028
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	43598022040
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	43598022114
AMOX/K	AMOXICILLIN & POT CLAVULANATE	43683010401
AMOX/K	AMOXICILLIN & POT CLAVULANATE	43683010501
AMOX/K	AMOXICILLIN & POT CLAVULANATE	43683010920
AMOX	AMOXICILLIN & POT CLAVULANATE	49884014227
AMOX	AMOXICILLIN & POT CLAVULANATE	49884014228
AMOX	AMOXICILLIN & POT CLAVULANATE	49884014247
AMOX	AMOXICILLIN & POT CLAVULANATE	49884016827
AMOX	AMOXICILLIN & POT CLAVULANATE	49884016828

AMOX	AMOXICILLIN & POT CLAVULANATE	49884016847
AMOX	AMOXICILLIN & POT CLAVULANATE	49884020128
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AMOX	AMOXICILLIN & POT CLAVULANATE	49884020170
AMOX	AMOXICILLIN & POT CLAVULANATE	49884029807
AMOX	AMOXICILLIN & POT CLAVULANATE	49884029812
AMOX	AMOXICILLIN & POT CLAVULANATE	49884029907
AMOX	AMOXICILLIN & POT CLAVULANATE	49884029912
AMOX	AMOXICILLIN & POT CLAVULANATE	49884036507
AMOX	AMOXICILLIN & POT CLAVULANATE	49884036581
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	49999017714
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	49999017720
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	49999021320
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	49999024620
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	49999035600
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	49999036550
AMOX/K	AMOXICILLIN & POT CLAVULANATE	50090082100
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	50090082101
AMOX/K	AMOXICILLIN & POT CLAVULANATE	50090082102
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	50090082103
AMOX/K	AMOXICILLIN & POT CLAVULANATE	50090082105
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	50090083100
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	50090083200
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	50090092800
AMOX/K	AMOXICILLIN & POT CLAVULANATE	50090099600
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	50090185700
AMOX/K	AMOXICILLIN & POT CLAVULANATE	50090231405
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	50090254700
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	50090254701
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	50090254702
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	50090254703
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	50090304700
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	50090317900
AMOX/K	AMOXICILLIN & POT CLAVULANATE	50090317901
AMOX/K	AMOXICILLIN & POT CLAVULANATE	50090317902
AMOX/K	AMOXICILLIN & POT CLAVULANATE	50090317903
AMOX/K	AMOXICILLIN & POT CLAVULANATE	50090317905
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	50090329300
AMOX/K	AMOXICILLIN & POT CLAVULANATE	50090330900
AMOX/K	AMOXICILLIN & POT CLAVULANATE	50436100101
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	50436312901

AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	50436605101
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	50436605103
AMOX	AMOXICILLIN & POT CLAVULANATE	51079026501
AMOX	AMOXICILLIN & POT CLAVULANATE	51079026520
AMOX	AMOXICILLIN & POT CLAVULANATE	51079026701
AMOX	AMOXICILLIN & POT CLAVULANATE	51079026720
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52246010715
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52246010721
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52246010821
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52246019521
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52493007730
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52493008030
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52493008101
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52493008103
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52493008201
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52493008203
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52493008315
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52493008321
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52493008330
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52493008415
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52493008421
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959002114
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959002115
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959002120
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959002121
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959002130
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959002230
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959025600
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959034309
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959034315
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959034321
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959034330
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959047030
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959047810
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959047814
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959047820
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959061600
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959061601

AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959061602
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959061700
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	52959070204
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	52959070209
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	52959070212
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	52959070214
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	52959070215
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	52959070220
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	52959070221
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	52959070230
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	52959070240
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	52959070710
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	52959070714
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	52959070715
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	52959070720
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	52959070730
AMOX/K	AMOXICILLIN & POT CLAVULANATE	52959070760
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959079328
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959079340
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959101200
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959101201
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	52959143100
AMOX/K	AMOXICILLIN & POT CLAVULANATE	53002023920
AMOX/K	AMOXICILLIN & POT CLAVULANATE	53002078920
AMOX/K	AMOXICILLIN & POT CLAVULANATE	53217007820
AMOX/K	AMOXICILLIN & POT CLAVULANATE	53217022001
AMOX/K	AMOXICILLIN & POT CLAVULANATE	53217028601
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	53261005293
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	53261008593
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54124060420
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54124060715
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54124060716
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54124060720
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54124060722
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569011700
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569012000
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569012100
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569012101
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569012102

AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569012103
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569013600
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569013603
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569014200
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569014203
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569029800
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569029801
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569101900
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569195900
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569195901
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569195902
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569195903
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569195904
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569195905
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569195906
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569195908
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569196202
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569196203
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569196204
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569432500
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569433700
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569433800
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569433801
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569435200
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569435300
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569445801
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569445802
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569488900
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569489200
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569501900
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569531400
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569534400

AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54569547000
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54569547001
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54569547002
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54569547003
AMOX/K	AMOXICILLIN & POT CLAVULANATE	54569547004
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54569547100
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54569547101
AMOX/K	AMOXICILLIN & POT CLAVULANATE	54569547102
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54569547103
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54569547104
AMOX/K	AMOXICILLIN & POT CLAVULANATE	54569547105
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54569548700
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54569548800
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569549900
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569551800
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569552200
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54569563800
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54569563801
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54569568900
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54569569000
AMOX/K	AMOXICILLIN & POT CLAVULANATE	54569583100
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54569604300
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54569800200
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54868019900
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54868019902
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54868019903
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54868020000
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54868020001
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54868028600
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54868038700
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54868038701
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54868038702
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54868038801
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54868170901
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54868390300
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54868390301

AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54868390302
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54868390303
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54868408000
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54868420800
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54868447100
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54868473502
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54868474300
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54868474301
AMOX	AMOXICILLIN & POT CLAVULANATE	54868474302
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54868495100
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54868495101
AMOX/K	AMOXICILLIN & POT CLAVULANATE	54868495102
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54868495103
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54868495104
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54868499000
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54868516500
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54868516501
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	54868517500
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54977003030
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54977040701
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54977040702
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	54977040801
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	55045125805
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	55045125807
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	55045134503
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	55045134507
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	55045134803
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	55045134807
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	55045137308
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	55045137808
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	55045147808
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	55045244607
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	55045295302
AMOX	AMOXICILLIN & POT CLAVULANATE	55045295304
AMOX	AMOXICILLIN & POT CLAVULANATE	55045295305

AMOX	AMOXICILLIN & POT CLAVULANATE	55045295307
AMOX	AMOXICILLIN & POT CLAVULANATE	55045295308
AMOX/K	AMOXICILLIN & POT CLAVULANATE	55045296500
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	55045296501
AMOX	AMOXICILLIN & POT CLAVULANATE	55045296603
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	55045296607
AMOX/K	AMOXICILLIN & POT CLAVULANATE	55045315607
AMOX/K	AMOXICILLIN & POT CLAVULANATE	55045335500
AMOX/K	AMOXICILLIN & POT CLAVULANATE	55045335501
AMOX/K	AMOXICILLIN & POT CLAVULANATE	55045368101
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	55175121900
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	55175121901
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	55175121905
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	55175122000
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	55175122002
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	55175122005
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	55175602101
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	55289051228
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	55289076710
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	55289076714
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	55289076720
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	55289076721
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	55289076728

AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	55289076730
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	55289084506
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	55289084520
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	55289084521
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	55289084528
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	55289084530
AMOX/K	AMOXICILLIN & POT CLAVULANATE	55700008120
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AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	55700010620
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AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	55700030614
AMOX/K	AMOXICILLIN & POT CLAVULANATE	55700030620
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	55700037515
AMOX/K	AMOXICILLIN & POT CLAVULANATE	55700037520
AMOX/K	AMOXICILLIN & POT CLAVULANATE	55700041820
AMOX/K	AMOXICILLIN & POT CLAVULANATE	55700044420
AMOX/K	AMOXICILLIN & POT CLAVULANATE	55700045614
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	55700047125
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	55700053875
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	55700065314
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	55700065320
AMOX/K	AMOXICILLIN & POT CLAVULANATE	55700075120
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AMOX/K	AMOXICILLIN & POT CLAVULANATE	55887021620
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	57362032419

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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	57362060234
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	58016051220
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	58016100001

AMOX/K	AMOXICILLIN & POT CLAVULANATE	58016100201
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	58016100801
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	58016480801
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AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	58016486901
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	58016499001
AMOX/K	AMOXICILLIN & POT CLAVULANATE	58118001701
AMOX/K	AMOXICILLIN & POT CLAVULANATE	58118001907
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AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	58864076720
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	58864077730
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	59651002601
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	59651002655
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	59651002675
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	60346059021
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AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	60432006547
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	60432006575
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	60432007046
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	60432007048
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	60432007075
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	60505253903
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	60505254002
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	60505254102
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	60713006214
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	60713006215
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	61919002020
AMOX/K	AMOXICILLIN & POT CLAVULANATE	61919020210
AMOX/K	AMOXICILLIN & POT CLAVULANATE	61919020220
AMOX/K	AMOXICILLIN & POT CLAVULANATE	61919039132
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AMOX/K	AMOXICILLIN & POT CLAVULANATE	61919043020
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	61919052120
AMOX/K	AMOXICILLIN & POT CLAVULANATE	61919063720
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	61919066514
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AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	63187001420
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	63187032720
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AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	63187042314
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	63187042320
AMOX/K	AMOXICILLIN & POT CLAVULANATE	63187042328
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	63187048820
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	63187080320
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	63187082600
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	63187085720
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	63187085775

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AMOX/K	AMOXICILLIN & POT CLAVULANATE	63629289501
AMOX/K	AMOXICILLIN & POT CLAVULANATE	63629289502
AMOX/K	AMOXICILLIN & POT CLAVULANATE	63629289503
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AMOX/K	AMOXICILLIN & POT CLAVULANATE	63629423901
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	63874024920
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	63874024930
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AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	65862050130
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	65862050220
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	65862050301
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	65862050320
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	65862053301
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	65862053350
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	65862053375
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	65862053401
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	65862053450
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	65862053475
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	65862053502
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	65862053513

AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	65862053575
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	66116015214
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	66116024030
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	66116067820
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	66116067930
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	66116068015
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	66116068130
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	66116068220
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	66267044415
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	66267071203
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	66267071210
AMOX/K	AMOXICILLIN & POT CLAVULANATE	66267071214
AMOX/K	AMOXICILLIN & POT CLAVULANATE	66267071221
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AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	66267085704
AMOX/K	AMOXICILLIN & POT CLAVULANATE	66267085902
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	66267085903
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	66267085904
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	66267099120
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	66267099220
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AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	66267100201
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AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	66336036430
AMOX/K	AMOXICILLIN & POT CLAVULANATE	66336036444
AMOX/K	AMOXICILLIN & POT CLAVULANATE	66336036806
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AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	66685101201
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	66685101202

AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	68030604201
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AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	68071422402
AMOX-CLAV	AMOXICILLIN & POT CLAVULANATE	68071496702
AMOX	AMOXICILLIN & POT CLAVULANATE	68084023501
AMOX	AMOXICILLIN & POT CLAVULANATE	68084023511
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AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	68115099020
AUGMENTIN	AMOXICILLIN & POT CLAVULANATE	68115099120
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MOXIFLOXACIN	MOXIFLOXACIN HCL	72789008010

Appendix E. Administrative Codes used to Identify Febrile Neutropenia (FN) and Treatment-emergent Adverse Events (TEAEs) Associated with G-CSF Prophylaxis.

Outcome*	ICD-10 Code*
Febrile neutropenia*	D70.1; D70.x, R50.2
Acute respiratory distress syndrome	J80
Capillary leak syndrome	I78.8, I78.9
Cutaneous vasculitis	L95.0, L95.1, L95.8, L959
Glomerulonephritis	N00.9
Leukocytosis	D72.820-D72.825
	D72.828
	D72.829
Serious allergic reaction (including anaphylactic shock)**	T45.1X5A
	T45.1X5D
	T45.1X5S
Splenic rupture	D73.5
Thrombocytopenia	69.5, 69.6
*Febrile neutropenia is an outcome related to chemotherapy administration and for this analysis is measured as an outcome relative to G-CSF administration comparisons	