PROBLEM DESCRIPTION

There exists an important public health need for active and systematic post-marketing evidence generation for biologics, including their corresponding biosimilar products.

GOAL

To develop an infrastructure to enable active surveillance of the real-world safety and effectiveness of originator biologics and biosimilars.

OBSERVATIONS

Since its formation, BBCIC has conducted four descriptive studies examining:
- Usage and rates of infections among patients with autoimmune diseases receiving anti-inflammatory biologics
- Treatment patterns and outcomes of adult patients with diabetes who use long-acting or intermediate-acting insulins
- Feasibility of BBCIC data to conduct a comparative study of erythropoietin stimulating agents (ESA) in hemodialysis patients
- Granulocyte-colony stimulating factors (G-CSF) use in breast and lung cancer patient who received chemotherapy with Grade III or IV neutropenic risk.

Each study was led by a team of BBCIC investigators overseen by a multidisciplinary group of stakeholders.

PROGRAM DESCRIPTION

The Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) is a non-profit initiative created in 2015 under the auspices of the Academy of Managed Care Pharmacy (AMCP). The BBCIC is a participant-supported and funded organization; participants include data partners (in-kind contributions), product manufacturers, managed care organizations, and other non-profit organizations who contribute annual fees. The Consortium uses a distributed research network (DRN) approach that includes medical and pharmacy claims data on more than 100 million patient lives to perform ongoing analyses of biosimilars and their innovator products.

BBPIC leverages the Sentinel Initiative to improve the efficiency and cost-effectiveness of post-marketed observational studies. BBCIC actively monitors biosimilars and originators through anonymous data from >100 million patients. BBCIC is a multi-stakeholder collaboration with diverse expertise allowing for a larger voice with more credibility.

FINDINGS/RECOMMENDATIONS

The AMCP BBCIC strategy provides a unique opportunity for Managed Care to support public knowledge of biologic and biosimilar drugs with robust science.

ACKNOWLEDGEMENTS/Sponsorship

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The BBCIC has generated data for each of the four descriptive studies, issuing over 40 queries across the DNA. The established infrastructure and experience from these descriptive analyses position the Consortium well for future analyses to generate real-world evidence for novel biologics and biosimilars.