able, health plans in some instances may seek to develop their own evidence. Although this can be challenging, our project provides an example of the feasibility of such an undertaking.

SYNAGIS 2005–2006 SEASON
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Organization: Horizon Blue Cross Blue Shield of New Jersey.

Problem or Issue Addressed: Synagis for RSV.

Goals: To assess retrospective rate of RSV hospitalization and/or ER visit in members who were approved for Synagis for the season and in members who were denied Synagis for the season.

Outcomes items used in the decision: Horizon criteria for Synagis is based on the AAP guidelines for RSV.

Implementation Strategy: After the peak RSV 2005–2006 season was over, Horizon did a retrospective analysis on all members who requested for Synagis. We reviewed the medical data for claims of RSV hospitalization, RSV ER visits, or RSV office visits. We pulled the following diagnosis: Respiratory syncytial virus –079.6; Respiratory syncytial virus, bronchiolitis –466.11; and Respiratory syncytial virus, pneumonia –480.1

Results: We had a total of 1028 members request for Synagis. Out of which 338 members (32.9%) did not meet the criteria and 690 members (67.1%) did meet the criteria. Out of the 338 members, 6 members (1.8%) had documented claim of RSV infection. They include the following:

• 1 patient was suspected for an admission
• 1 patient was denied and 7 days after had a hospitalization
• 1 patient was denied and 12 days after had a hospitalization
• 2 patients were denied AFTER the hospitalization
• 1 patient seemed to have a RSV hospitalization

Lessons Learned: Horizon’s Synagis criteria is based on the AAP guidelines.

We will continue to monitor for RSV related hospitalization, RSV related ER visits, and RSV related office visits every season.

DETERMINING THE VALUE OF DIAGNOSTIC/GENETIC TESTING TO INFORM HEALTH PLAN DECISION MAKING: ONCOTYPE DX AS A CASE STUDY
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Organization: Premera Blue Cross Pharmacy and Therapeutics Committee (P&T). Premera is a 1.6 million member regional commercial health plan in the Pacific Northwest.

Problem or Issue Addressed: Need to determine medical necessity criteria and appropriate cost-effective use of Oncotype DX, a genomic test that predicts the risk of distant recurrence following successful surgical resection of early stage, node negative, estrogen receptor positive breast cancer.

Goals: To pilot the use of disease-based cost-effectiveness models in helping medical policy decision makers to determine the appropriate place in therapy for a genomic diagnostic test that is the first of many similar products to reach market.

Outcomes items used in the decision: The assessment for the decision will include evaluating the available body of clinical and economic evidence. Information related to cost-effectiveness will be evaluated from the published literature and from evidence provided from the sponsor company to the health plan, following an unsolicited request for this information. The health plan requested that the evidence package follow the suggested approach outlined in a 2006 University of Washington, Pharmaceutical Outcomes Research and Policy Program and Public Health Genetics Program joint-guidance document, “Evidence and Transparency Recommendations to Support Coverage and Reimbursement Decisions for Medical Testing.” The specific outcomes to be evaluated for the diagnostic are the clinical effects and the reliability of the test, economic endpoints related to the cost of improving overall survival and quality-adjusted survival, and the sensitivity analyses presented in published economic models supporting the product. The guidance document suggests a presentation of clinical information, as well as information on the costs and consequences and/or cost-effectiveness of new medical testing technologies.

Implementation Strategy: The case study evaluation process consists of four primary stages. First, a preliminary review of evidence was performed using published literature and the initial product-related information provided by the sponsor company. Second, a full evidence support dossier was requested from the sponsor and will be evaluated by the research team. Third, additional assessments and sensitivity analyses will be performed to identify meaningful metrics for product evaluation moving forward. Fourth, the results are to be presented to the Pharmacy and Therapeutics Committee for scientific review, and then to the Medical Policy Committee, where the final decision is made. The resulting policy will then be implemented through Premerra’s routine medical necessity review process.

Results: The preliminary clinical and economic evaluations suggest that additional evidence would be helpful to more fully inform health plans regarding coverage and reimbursement decisions. The sponsor company response to the product information request (i.e., dossier) is expected to assist the health plan with evaluating the most recent and complete available Oncotype Dx-related evidence. The evidence presentation format suggested in the medical testing guidance allows a product developer the opportunity to describe and present information related to the clinical and economic value of their products. An evaluation of the economic model parameters for which the cost-effectiveness estimates are most sensitive (e.g., lower-risk recurrence score patients receiving adjuvant chemotherapy treatment) can provide ranges of cost-effectiveness related to the expected value of the diagnostic test, depending on whether the test results influence changes in clinical behavior (i.e., forgoing chemotherapy).

Lessons Learned: Clinical-effectiveness and cost-effectiveness evaluations for medical diagnostic products are increasing in rigor and in the expectations of health plans for evidence of clinical utility. The value of utilizing higher-priced medical products for serious illness can be strengthened when diagnostics can assist with the identification of appropriate patient sub-populations and the likelihood and expected magnitude of clinical and economic response. However, new diagnostics tend to have less evidence for evaluation compared to new pharmaceuticals. Provided that most medical products have limited real world effectiveness data at launch, which may take years to accumulate, effectiveness modeling can be useful to aid decision-making. Evaluating the evidence for Oncotype Dx in relation to its clinical and economic net benefit to patients serves as a useful case for piloting the evidence guidance document and for considering the health and economic effects of diagnostic testing for difficult to treat and recurring diseases, such as breast cancer. Standardizing the process for and improving the transparency of evidence evaluation for medical tests should contribute to more efficient and consistent resource allocation.