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Validation of an Algorithm to Identify Romosozumab in Health Plan Claims Data Shortly After FDA Licensure

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PURPOSE & OBJECTIVES

- Shortly after licensure, parenteral medications administered by healthcare providers are often assigned non-specific procedure codes for reimbursement purposes. This lack of specificity can create challenges in identifying new therapies in administrative data sources such as Medicare claims data.
- We developed and validated a claims-based algorithm to identify romosozumab, a biologic approved in April 2019 for women with osteoporosis.

MATERIALS & METHODS

- We used national U.S. Medicare claims data from 04/01/2019 to 12/31/2019 for all women with osteoporosis (based on ICD10 diagnosis, prior fracture, or medication). We then linked the claims data to electronic medical record (EMR) data from Illumination Health, a community rheumatology practice-based research network (PBRN) and one of the data partners of OneFlorida+, a member of PCORnet.
- We developed a deterministic algorithm using claims data that identified all non-specific Healthcare Common Procedure Coding System (HCPCS) codes (J3490, J3590) suggestive to be romosozumab, applying additional criteria including:
  - ✓ Diagnosis criteria: osteoporosis diagnosis codes (M80.*, M81.*) in the same claim,
  - ✓ Allowed (payment) amount or dose criteria: for claims meeting #1, require allowed amounts of exactly $1879, $1934, $967, and $939, or units equal to 210mg,
  - ✓ Dosing interval criteria: for claims meeting #1 but not #2, remove claims with specific HCPCS codes indicating other osteoporosis drugs (e.g. zoledronate, denosumab) or surgery-related medications (conscious sedation, parenteral opioids) that might use the non-specific HCPCS codes; then require a dosing interval between 28 to 35 days.
- We compared results from the algorithm to manual review of all physician notes and nursing administration records from the EMR to confirm whether romosozumab was given. Further, to assess what other therapies may have used non-specific HCSPCS codes in this time frame, we searched the EHR of the rheumatology providers in the network for all drugs billed under J3490 and J3590 plus all prescribing data for physician orders for romosozumab. 95% confidence intervals (95% CI) were computed using a binomial approximation.

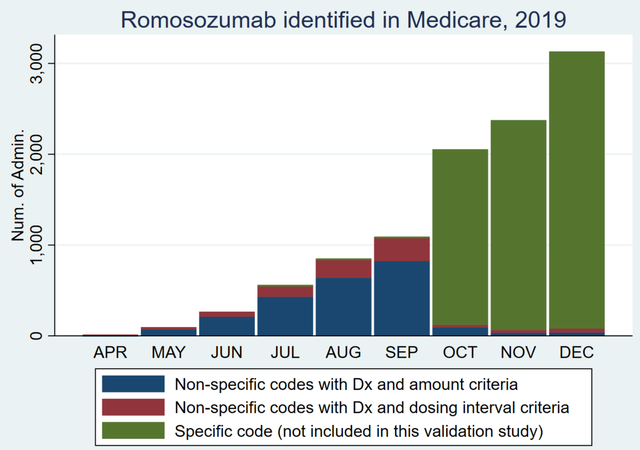

Figure.
Romosozumab identified in Medicare claims data using non-specific code algorithm and its specific HCPCS code (J3111).

CONCLUSIONS:

- ❑ Romosozumab can be validly identified in administrative health plan claims data even before its specific medication administration code (J3111) became widely used in Q4 2019.
- ❑ This approach is likely to be useful for pharmacovigilance studies that characterize the use and safety of new medications administered by providers.
- ❑ Failure to implement an approach such as this will underrepresent the number of early users of romosozumab and misclassify the date of first use.

RESULTS

- We identified 47,452 records of J3590 or J3490 with diagnosis codes M80.* or M81.* in the same claim. Among these, 2,337 met the allowed amount criteria. Combined with dosing interval criteria, a total of 3,123 possible romosozumab administrations were identified in Medicare data based on the algorithm, among 1,418 unique patients.
- We then identified 110 possible romosozumab administrations of Medicare when linked to EMR data. Following medical record review, the PPV of the romosozumab claims-based algorithm was 99.1% (109/110), 95% CI 95.0% - 99.9%. The substantial majority (n=101, 92.7%) were administered in the network rheumatologists' offices.
- Based on the independent search of the EMR for all J3490/J3590 codes, physician orders for romosozumab and medical record review in the linked sample, we identified 117 records confirmed to be Romo. The sensitivity of the claim-based algorithm was (109/117 = 93.2%, 95% CI: 87.0% - 97.0%).
- In EMR data, for all J3490/J3590 codes, the substantial majority (94.4%, 95%CI 88.2% - 97.9%) were for romosozumab; few were miscoded that identified other therapies (e.g. traumeel, a non-cortisone injectable treatment for musculoskeletal pain).
- Use of the specific administration code (J3111) had rapid uptake beginning October 2019 (Figure).

STRENGTHS & LIMITATIONS

- Multiple data features including diagnosis codes, dose, allowed (payment) amounts, and dosing intervals were integrated to identify romosozumab, and a large linked data source with structured and unstructured EMR data for validation.
- No 2019 Part D data was yet available at the time of this analysis. Although most patients were expected to receive romosozumab under part B (the Medicare medical benefit), refinement of the algorithm to incorporate Part D data could improve the sensitivity and PPV.
- This validation was conducted using the EMR data from a national network of community rheumatologists. Performance of the algorithm may differ if romosozumab is administered in other settings.

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