CMS-1670-P: Grim gross margins of 1.8%-3.7% at proposed reimbursement and after sequester for cancer chemotherapy regimens + supportive care drugs (see PDF of analytic spreadsheet)

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March 19, 2016

Posted at the resources tab at EB Rubinstein Associates website (www.ebrubinsteinassociates.com/resources.html), are topline results of a reimbursement analysis of a CY 2014 Part B claims data file posted to the CMS website, linked to April 2016 ASPs and to examples of all-generic and mixed generic/brand 1st line cancer chemotherapy regimens recommended in 2016 NCCN guidelines for Non-Small Cell Lung Cancer, Breast Cancer and Colon Cancer. To provide a 'whole patient' perspective, drugs used to prevent emesis and neutropenia - common side side effects of the modeled chemotherapy regimens - are included in the analysis. Average dose modeled per drug is as calculated per the CMS claims data file, not as recommended in NCCN guidelines.

Calculated gross margins calculated at the proposed reimbursement of ASP+2.5%+$16.80/drug/day are grim after application of the Congressionally-mandated sequester: Gross margins for chemotherapy regimens for non-small cell lung cancer, breast cancer and colon cancer, including supportive care drugs, range from 1.8%-3.3% across chemotherapy regimens that include brand+generic drugs administered on the first therapy day (including in the calculation drug used for prevention of neutropenia, which would be administered the following day). Using the same assumptions, gross margins for generic-only chemotherapy regimens generated slightly higher gross margins of 2.3%-3.7%.

These results assume that providers or specialty pharmacies are able to acquire product at ASP. This may be an incorrect assumption for smaller oncology practices due to lack of leverage, and for specialty pharmacies which are disadvantaged in their purchase of single source drugs because they are typically considered part of the retail "class of trade" (see Robinson-Patman Act of 1936) which is rarely afforded discounts on such products, particularly if they have no therapeutic competitors. If unable to acquire these products at ASP, gross margins would be significantly reduced.

If CMS-1670-P is finalized as written, smaller community medical practices may refer patients to hospital-affiliated 340B clinics, which according to MedPAC's March 2016 Report to the Congress, are able to acquire drug at an average of 34% below ASP. Can larger medical oncology practices maintain their infusion suites at this level of reimbursement, particularly if private sector payers follow CMS' lead?

Might community medical oncologists refer to specialty pharmacy infusion suites? But if that occurs, can large drug chains and pharmacy benefit manager owned specialty pharmacies and infusion suites survive this level of reimbursement, particularly if they cannot acquire single source brand products at ASP, since it is those products, not the multisource generics in the chemotherapy regimen, which will drive margin dollars?

Might large drug chains and specialty pharmacies be willing to accept such small gross margins for payers willing to reimburse them for supply or infusion of 'incident to' drugs, despite concerns such as potential bad debt and cash flow, in order to gain access to the patient? If yes, how can smaller, less diversified specialty pharmacies with fewer resources compete?