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JPM 2024: Health Policy Takeaways

Minimal IRA Concern, Obesity, Alzheimer's, ARPA-H, Oncology, Clin Labs, PBM

Relevant Companies: All Healthcare

Our Take & Next Up

Policy takeaways from this week's JPMorgan conference can be found below. This week, J.P. Morgan is hosting the annual Healthcare Conference that brings investors and industry leaders to discuss innovation, policy trends and general capital markets sentiment e.g., excitement over recent Biotech performance. We highlight commentary on Biopharma, PBMs, Alzheimer's, Obesity, Oncology, Diagnostics, and Clinical Labs. There was less robust participation from health plans but salient PBM commentary is included.

Key Points

Drug negotiation is not a notable area of concern for large biopharma at the conference. Instead, companies headline other near-term headwinds. As a reminder, the manufacturers of the first set of negotiation drugs are expected to see an initial offer next month (by Feb 1). The upcoming patent cliffs of major products (BMY, MRK) were a more discussed headwind in remarks at JPM.

- BMRN drew attention to their "IRA insulated" core business when reassuring investors of their refocus.
- NVO noted their diabetes products will face IRA inflationary rebates, but predicted they would still have volume runway for their GLP-1 products even with IRA impact.

Ionis mentioned that the Part D redesign (in 2025) is helpful to the portfolio, helping with patient affordability. As a reminder, the Part D rule in January will focus on the newly restructured benefit, per IRA.

- A new $2,000 out-of-pocket spending cap for seniors should alleviate OOP pain particularly those who are chronically ill on polypharmacy.
- Elimination of the coverage gap "donut hole" phase
- Health insurers will be on the hook for 60% in the catastrophic phase (versus 15% today).
- The government is currently responsible for 80% and that moves to 20% for brand & 40% for generics above the OOP threshold.
- Manufacturers will be required to provide a 20% discount on brand-name drugs above the OOP cap.

The newest biomedical federal agency made announcements at JPM: ARPA-H preventable death program launch (here) intends to reward private investments in local populations. Set to start in Q1 2025, the program will enroll local organizations that will take accountability in improving specific measures of preventative deaths. There are four measures floated by the agency with 2 expected to be selected: severe obstetric complications, alcohol-related health problems, opioid overdose, and cardiovascular disease and

stroke risk. Sites will be reimbursed $15 M in advanced purchasing to incentivize finding methods to lower the prevalence of the selected measures.

OBESITY

Medicare coverage of GLP-1s (obesity) is expected to improve with additional non-obesity indications (CV, sleep apnea) while US lawmakers slowly open to Medicare obesity coverage 2025+. Medicare coverage for obesity is not likely to occur in 2024 due to lack of movement on the *Treat and Reduce Obesity Ac*t (TROA). However, CMS coverage is predicted to expand near-term from additional non-obesity indications. Cardiovascular indications are expected for Wegovy (NVO) and data for sleep apnea & heart failure are expected in 2024 for Zepbound (LLY). As Medicare coverage expands, GLP-1 net prices are expected to shift down for government payers.

Ten states through Medicaid cover the GLP-1s for obesity, with the UK's NICE covering for only 2 years. 2-5% of Americans take obesity drugs and 40% of employers provide coverage. Interestingly, the UK authorizes usage for two years (versus more of a chronic disease approach), which is concerning for payers. ICER noted at a keynote panel that the cost-value proposition improves when an expensive obesity drug is used longer-term.

ALZHEIMER'S

LCDs for Medicare PET scan coverage for Alzheimer's are moving faster than expected. PET scan usage is up, indicating the increased Leqembi demand and shifting diagnostics procedure for Alzheimer's. BIIB noted that Medicare Administrative contractors are moving quite rapidly by holding meetings at atypical times to discuss LCD coverage.

The next frontier for Alzheimer's therapies is expanding to earlier stages of the disease, potentially even prevention. As a reminder, Leqembi (and if approved, Donanemab) treat a fraction of the total population impacted by Alzheimer's disease. Both LLY & BIIB hope to take therapies into the early stages of Alzheimer's disease to take advantage of the better efficacy in patients with earlier stages. Companies are also discussing moving toward a prevention regimen. If therapies do move into earlier stages, the current CED framework may be revisited to address access in the future.

ONCOLOGY

State biomarker laws (covering 50% of the US population) that will be implemented in 2024 are expected to improve commercial reimbursement for cancer diagnostics. Biomarker laws require commercial plans to cover biomarker testing in indications that are already covered by Medicare (particularly for cancer care). Commercial biomarker coverage most recently passed in NY. Other states with biomarker laws include AZ, CA, IL, LA, RI, KY, NM, MD, MN, TX, GA, AR, OK. Supporters of biomarkers laws are largely providers & patient groups, including the Association of Community Cancer Care Centers, the American Cancer Society, NORD, and NCCN.

CMS is monitoring oncology diagnostics access through controversial LCDs (Novitas & First Coast). The agency is looking to release their criteria on prior authorizations and looking at ways to ensure uniformity of coverage on diagnostics between MA and FFS. The agency is also monitoring the proposed Local Coverage Determinations (LCDs) on genetic testing for oncology from Novitas & First Coast. The LCDs set a "default" non-coverage for genetic tests that are not included on one of three knowledge bases (NCCN, ClinGen, OncoKB).

Few companies we heard from discussed the proposed FDA LDT pathway. As a reminder, FDA laid out a pathway in the fall, sought comments, and will finalize in 2024 (by April). We predict that without major revisions to the lab-developed test clearance pathway upon finalization that the agency will be sued, with Congress potentially hashing out the pathway (recall VALID Act) if FDA is halted in its tracks.

PBM

Pending Congressional PBM bills are more targeted, plans continue to react to pressure from policymakers with homegrown solutions (CI, CVS). The more targeted anti-PBM reforms were noted by companies as being better for the industry. Both CI and CVS continue to tout new transparency programs with an emphasis on client choice. On client preference, unbundling of PBM benefits seen with Blue Shield of California earlier this year is not expected to be prevalent as not many clients have the sophistication to manage several PBM services provided by different vendors.

As a reminder, we predict that several of anti-PBM provisions passed by the various committees (House E&C, Senate HELP & Finance) are likely to pass in 2024, but less meaningfully impact the business model. On which reforms are most likely to pass, we expect lawmakers to prioritize Part D/MA transparency (possible in commercial), Medicaid spread pricing ban, and potentially even a newer idea, or "de-linking" reimbursement, with possible DIR fee reform.

CLINICAL LABS

On clinical labs, the SALSA Act may make it into an end-of-year healthcare package (lame duck). This would be positive for LH, DGX. While movement on a large legislative package is unlikely during the lame duck post-election period of Congress, there is a desire for a permanent solution to the laboratory fee cuts. Members of Congress are tired of continuously delaying PAMA cuts each year.

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