November 19, 2015

Ms. Caroline Pearson
Avalere Health
1350 Connecticut Ave, NW
Washington, DC 20036

Re: Misleading Avalere Report on Patient Access to HIV Drugs in Exchange Plans

Dear Ms. Pearson:

As the Chief Actuary for Covered California, the Health Insurance Exchange for the State of California, I am surprised and disappointed by the recent report Avalere prepared for Gilead Sciences on Patient Access to HIV Drugs in Exchange Plans published November 11, 2015. The issues regarding how best to cover needed prescription drugs for those with serious and chronic conditions – especially for high cost drugs – is an important issue that deserves thoughtful analysis and patient-centered policies. Covered California has sought to develop and evolve its benefit designs using both. I am sharing these comments with our board and the public because the issues raised are ones that Covered California has been addressing since our inception in a transparent and constructive way while the misleading nature of the analysis is deeply troubling and does little to foster factually informed policy making.

Unfortunately, the Avalere report is so fraught with methodological problems and biased framing of the "issue" that, rather than provide helpful light on a complex topic, it instead appears to present a conclusion that benefits only pharmaceutical companies – such as the report's sponsor – without analysis of the actual experience faced by people living with HIV/AIDS in the nation's Exchanges or of the actual strategies and the rationales behind those strategies being considered by both Exchanges and purchasers in general. The report was indeed successful at generating many headlines such as "Obamacare Plans Offer Limited Access to HIV Drugs." The report's success at grabbing headlines that play into the misunderstanding of the scope and nature of prescription drug coverage in Exchanges, is not matched by the rigor and thoughtfulness required of this important issue.

At Covered California, we have taken actions as an "active purchaser" to continuously assess and assure access to high-priced drug therapies so that all of our enrollees with chronic illnesses have access to necessary drugs while maintaining high value

insurance policies. We believe that continual assessment and improvement of benefit designs should be part of any responsible purchaser's ongoing strategy. As part of our response to your report, below we summarize both the prescription drug benefit designs in place in 2015 and changes made for 2016 that reflect actions taken for all enrollees, including those with HIV/AIDS.

As described below, there are several elements in the methodology and other elements of the report that appear to misrepresent or understate the actual positive nature of the coverage of Exchange Plans for people with HIV/AIDS. We are clear about the extent to which the methodology and analysis misrepresent the reality of coverage in Covered California, but can only assume the same would be the case for many other states. It is important for a firm like Avalere to provide a balanced report, rather than a report that appears to be biased towards the interests of the company (and industry) that has funded the report.

Report Framing Reflects "More Is Always Better" Philosophy and Not How Most Plans and Purchasers Seek Higher Value for Consumers

The central framing of the report is that coverage for most or all potential treatments for a condition should be available to consumers at the lowest possible cost. Virtually all public and private purchasers have developed formularies that do NOT have ALL drugs of a particular class available at the lowest cost-sharing to consumers. The rationale for this practice to both steer consumers to the "best" of available treatments and to allow for better price negotiations from plans and purchasers with pharmaceutical companies. In private employer and public programs, there are and should be ready avenues by which consumers can get access to higher cost or off-formulary treatments that are better for them if lower cost alternatives are deemed clinically inappropriate treatment – often at lower tier pricing. Alternative structures – that seem to be implicitly endorsed by the "report" – that would offer ALL drugs in a class of treatment at low co-pays for consumers, would be a boon for already thriving pharmaceutical companies. They would not be a boon for the public, payers or for many patients that would be steered by marketing and advertising more than by what has been proven to work.

Analytic Problems with the Report

Central to the Avalere report, is the characterization of particular states as having "Full Access" vs. "Moderate Access" vs. "Restrictive Access." This characterization and how it was applied appear not only to be arbitrary, but designed to reach a particular conclusion. Examples of some of the problems include:

1. **The unverifiable methodology uses two independent factors to characterize plans.** The method of categorizing Silver plans by Full vs. Moderate vs. Restrictive uses either of two criteria (number of regimens OR cost-sharing amounts per month). As described below in the context of California, some Silver plans may indeed have 7-9 regimens or all 10 regimens but have higher cost-sharing on only some of these regimens. This apparently means that a plan that has many treatments covered at very low costs, would still be characterized

as "restrictive" if some are higher cost – even if access to those drugs is possible AT LOWER COST if needed. As you undoubtedly know, insurers are encouraged to use cost-containment techniques and bargaining with the pharmaceutical industry to do as much as they can to offer reasonable premiums for Essential Health Benefit coverage under the Affordable Care Act. By providing "channeling" of enrollees with HIV to make use of certain regimens with lower cost-sharing, insurers can better negotiate with pharmaceutical companies to contract at bigger discounts. Without this leverage, insurers might be forced to pay very high prices for drugs that may have equivalent medical effectiveness. Instead, insurers are able to save money for consumers by using these cost management techniques.

2. **Use of "Average Wholesale Cost" instead of actual costs.** As noted on p. 3 of the report, coinsurance dollar amounts were "estimated using averaged wholesale acquisition cost (WAC)" of the drug regiments. The footnote says these do not include discounts or rebates. Because all large insurers or their Prescription Benefit Managers (PBMs) engage in aggressive negotiation with pharmaceutical manufacturers, discounts which are generally part of the point-of-sale calculation for consumer cost-sharing are substantial for most drugs, and especially for those with several drugs in a treatment category. In my prior experience, the discounts might average 15-20 percent off the WAC that was used. Thus, the number of plans in the categories of Moderate and Restrictive would likely have moved "down" dramatically towards the less restrictive or Full Access categories. Avalere's failure to identify the implications and significance of this "simplifying assumption" is troubling.

3. **Distribution by "number of plans" versus where consumers are enrolled.** Throughout its analysis, Avalere making conclusions based on "number of plans" is especially problematic. While Covered California seeks to benefit consumers by limiting the number of plans on the "product shelf" in any Metal Tier (like the Silver Tier) to represent (generally) one or sometimes two plans per insurer, in most states, there can be a wild abundance of plans with very little enrollment. And, even in California, while there are ten plans statewide offering coverage – much of the enrollment is concentrated in a smaller number of plans – plans that generally had "less restrictive" access in 2015. As a common example that we cite, our Los Angeles regions have 7 Silver plans in the region offered by six carriers, while Denver and Miami have more than thirty plans offered respectively by six or eight carriers respectively. Counting each and every Silver plan across the United States suggests an issue which includes plans with very little enrollment in your counts. As discussed in terms of enrollment in California – showing enrollment would be an important addition to the analysis.

4. **Lack of discussion of cost-sharing subsidies means the analysis is not a fair representation of the benefits available to Exchange enrollees with HIV/AIDS.** A very important factor that makes the comparisons in the report misleading is the lack of discussion of Silver Cost-Sharing Reduction plans. As I'm sure you know, a substantial portion of consumers in exchanges across the

nation are eligible for premium subsidies AND for Cost-Sharing Reduction (CSR) plans if their income is below 250 percent of the Federal Poverty Level (FPL). In California, approximately two-thirds of the consumers with Silver plans benefit from cost-sharing reductions. For those with the highest subsidy – about ten percent of all enrollees – this means that in 2015 not only did they receive large premium support subsidies, but their share of drug costs was nowhere close to any relation to the "Average Wholesale Cost". (In California, with standard benefits – those with the highest cost-sharing subsidies pay per prescription respectively $3, $10 and $15 for Tiers One, Two and Three – and Specialty Tier Four is capped at $150 per prescription.) In comparing Exchanges to the federal AIDS Drug Assistance Program (ADAP) – which is means tested and only applies to people living with HIV/AIDS but NOT comparing those individuals' options to the high subsidy plans many consumers enroll in, either shows marked ignorance of how subsidies are structured or an intention to paint a picture that does not reflect the reality of many if not most consumers with HIV/AIDS in Exchanges.

5. **Framing of the data and conclusions appears geared to "headlines" not to foster better policy making.** The lead sentence of the Avalere summary is that "only 16percent of sliver exchange plans in 2015 cover all top HIV regimens with cost sharing of less than $100 per month" and the summary focused on the 57% of states with "restrictive" coverage. For all the reasons detailed above, these conclusions themselves seems highly questionable. But even if true, it is interesting to note that reporters and policy-makers' attention is NOT brought to the conclusion from the analysis that 79percent of all plans cover 9 or 10 of the common treatments and a "majority" (51 percent) of plans offer HIV drugs at "lower cost tiers" (PowerPoint #3, and this is without accounting for the cost-sharing reductions). While I understand that any analysis can pick and choose "cut-off points" or what to call to reporters attention, as the author of this report, you appeared to summarize the data in the most inflammatory way possible.

6. **Inaccurate representation of and comparison to employer-based coverage**. The comparison with employer sponsored insurance (ESI) provided on p. 3 of the report is short and incomplete. While it is true that ESI is generally richer than Silver plans that do not have the cost-sharing reductions (most ESI provides coverage in the Gold or "Gold-Plus" range, with approximately 15-20percent less cost-sharing than for Silver plans), no source of data is specified for the statement that "HIV drugs are widely covered on generic and preferred brand tiers and almost never placed on a specialty tier." Does this only describe ESI for large employers (say, covering over 1000 employees)? How does it compare for Small Employers (with 2-50 employees)? The further discussion of utilization management (UM) is incomplete (15 states) and without any date. As costs for all types of coverage have increased, employers have been at least as active in raising cost-sharing as any other type of coverage. Comparing the availability of prescription drug coverage in Exchanges to ESI is important and worth a full portrayal.

7. **Ignoring appeal and utilization processes that allow lower cost access.** In addition to standard Silver and Silver CSR benefits, all insurers in the U.S. have an appeals process to be used when prescription drugs on the formulary do not work for their enrollees. Upon appeal to the insurer, many patients are then granted access at standard cost-sharing rates to drug regimens that are not otherwise available on a plan's formulary. This is true in Covered California and other Exchanges across the nation, but was not referenced anywhere in your report.

8. **Absence of the new context for HIV/AIDS coverage.** Nowhere in the report does Avalere even allude to the new context for coverage of people with HIV/AIDS under the Affordable Care Act. Where a few short years ago, having an HIV diagnosis made individuals uninsurable, now not only must all plans accept individuals regardless of health status there is no longer a need to "avoid" HIV/AIDS patients under the Affordable Care Act. Risk Adjustment is the permanent risk stabilization program that shifts money from insurers with healthier enrollment to those which may be enrolling and treating people with more conditions. HIV/AIDS is one of the 100+ conditions that qualify a plan for extra risk adjustment payments for its enrollees. Thus, any insurer that has somehow avoided enrolling an average share of people with these diseases will pay into the state-wide risk adjustment pool and any insurer that enrolls more than the average amount (perhaps because it has better protocols for treating people with these conditions) will receive extra payments.

9. **Characterizing HIV/AIDS drug coverage through the Exchanges and ADAP as either/or options.** The report discusses drug coverage through the Exchanges "compared to other potential sources of coverage for people with HIV" and notes that ADAP formularies in 47 states cover all 10 commonly prescribed therapies. This presents the coverage options as for people living with HIV/AIDS as either/or, when in fact all Covered California enrollees under 400 percent FPL who meet other program criteria are eligible to receive full cost-sharing assistance for drug deductibles, copays, and coinsurance through the California's ADAP program, and enrollees from 400 to 500 percent FPL are eligible for partial assistance through ADAP. Moreover, enrollees up to 500 percent FPL who are enrolled in ADAP have been eligible to apply for premium assistance through the Office of AIDS Health Insurance Premium Payment (OA-HIPP) Program. In addition to full or partial coverage of medications, OA-HIPP will pay for an enrollee's premiums at any metal level. Given these dual coverage options for people living with HIV/AIDS, it is hardly the case that access to top HIV regimens in the California Exchange can be characterized as "restrictive." While ADAP eligibility criteria varies from state to state, in California this means that virtually all individuals with HIV/AIDS enrolled in Covered California have distinctly UN-restricted and very affordable access to prescription drugs.

Covered California's Reality – Good Coverage that is Getting Better

As a public entity that attempts to provide all California consumers with high value health plans and good coverage of Essential Health Benefits, Covered California seeks to provide access to appropriate care for all of our enrollees with any disease condition. Unlike ADAP programs that are subject to the whims of appropriations, exchange-based insurance is a permanent program under the Affordable Care Act funded from premiums collected.

Covered California, as an Exchange that is an "active purchaser," has chosen with the help of its stakeholders (consumers, insurers, and providers) to both standardize benefits and limit cost-sharing across the care continuum to be sure that out-of-pocket costs are not an undue barrier for consumers getting care. This is particularly true for expensive drugs, where Covered California has instituted policies so that consumers are not deterred from obtaining drug care for the condition they have. Policies were in place in 2015 that promoted standard design and access. Based on our review of the plans and benefits offered in California – not only does California not meet Avalere's description of "restricted access" – but the majority of Silver plans in other state Exchanges are likely to move to a less "restricted" category if the flawed Avalere methodology was revised to reflect the comments in this letter.

Beyond the current status, we are troubled that you have been cited in press coverage of your report as concluding that you "do not expect major changes in HIV/AIDS drug benefits for silver-level exchange plans sold for the 2016 coverage year." Covered California is the largest marketplace in the nation and the changes to our standard benefit design related to prescription drugs was widely covered in the media (See http://news.coveredca.com/2015/05/covered-california-board-protects.html). In particular, starting in 2016, all insurers in Covered California must offer some treatments at lower cost tiers where more than three treatments are available (as is the case in the top HIV/AIDS drugs studied), and we will limit cost-sharing to no more than $250 per script per month for a Silver plan for even those drugs that could cost many thousands of dollars. For all drugs in Covered California plans, coinsurance has already and will continue to be limited to 20% paid by consumers (some drugs are in copay tiers in some plans, rather than in a coinsurance tier). Thus, many HIV/AIDS drug regimens are already limited to less than $200 per month, since I believe that the average discounted monthly HIV/AIDS drug cost for Covered California plans is around $1,000 per month.

To illustrate the wide variety of prescription drug regimens available in Covered California plans for plan year 2016, please see Table 3 in the attachment to this letter (http://board.coveredca.com/meetings/2015/11-19/.Comments. You will see that 35 drug regimens are available in various plans in various drug cost-sharing tiers (Generic = 1, Preferred Brand = 2, Non-Preferred Brand = 3, Specialty = 4, with generic therapies highlighted in yellow). Consumers have a wide choice of plans and drug therapies in most of Covered California's 19 regions – and when you look at the drug choices based on where consumers enroll, the vast majority have many of the therapies available in drug tiers 1, 2 or 3, the copays are under $100 per script. Further analysis of the

Avalere "Top 10" is shown in Tables 1 and 2: most of the Covered California plans provide access to nearly all of the "Top 10" (as counted by Avalere's source, not necessarily the drug therapies used by California patients) and many are available in the Preferred or Non-Preferred Brand tiers, at less than $100/script cost-sharing. As noted earlier, those plans providing coverage as Specialty drugs in Tier 4, are limited to charging 20 percent member cost-sharing up to $250/script in 2016. Labeling Covered California's Exchange as "Restrictive Access" appears not only to be incorrect, but appears to be part of pattern of misleading conclusions and analysis. A table representing a summary of the HIV/AIDS drug coverage for Covered California's plans in 2015 and 2016 offerings is shown below.

Covered California Coverage of 10 HIV/AIDS Therapies Highlighted by Avalere

2015 Coverage and Membership	**ANTHEM**	**BLUE SHIELD**	**CCHP**	**HEALTH NET**	**KAISER**	**LA CARE**	**MOLINA**	**OSCAR**	**SHARP**	**UCH**	**VALLEY**	**WHA**
Number of therapies covered (out of 10)	6	10	10	10	9	10	8		10		9	10
Number of therapies (out of 10) with cost share of $75 or less	6	10	0	10	9	0	8		0		0	10
Total Enrollment as of April 2015 (Percent)	28.1%	24.6%	0.9%	17.7%	23.9%	1.5%	1.6%		1.3%		0.2%	0.4%

Conclusions

- 9 plans, which represent 72.1% of membership, cover 7 or more therapies
- 6 plans, which represent 46.4% membership, cover all 10 therapies
- 6 plans, which represent 96.3% of membership, cover at least 6 therapies at $75 or less
- 3 plans, which represent 42.7% of membership, cover all 10 therapies at $75 or less

*The number of plans covering medications at $200 or less is unknown due to different negotiated drug prices by each health plan, which dictates the Tier 4 (specialty drug) coinsurance amount for the member. Roughly 90% of Covered California members have access to the AIDS Drug Assistance Program, which will pay for all of their HIV/AIDS therapy cost shares and insurance premiums. For more information visit: http://www.cdph.ca.gov/programs/aids/pages/tOAADAPIndiv.aspx

2016 Coverage (Membership pending)	**ANTHEM**	**BLUE SHIELD**	**CCHP**	**HEALTH NET**	**KAISER**	**LA CARE**	**MOLINA**	**OSCAR**	**SHARP**	**UHC**	**VALLEY**	**WHA**
Number of therapies covered (out of 10)	6	10	10	10	10	10	10	10	10	10	9	9
Number of therapies (out of 10) with a member cost share at $70 or less for Silver, Gold, and Platinum plan members	6	10	4	10	10	0	10	10	0	10	0	0
Total Enrollment as of April 2015 (Percent)	28.1%	24.6%	0.9%	17.7%	23.9%	1.5%	1.6%		1.3%		0.2%	0.4%

Conclusions

- 9 plans cover all 10 therapies
- 11 plans cover 7 or more therapies
- 6 plans cover all 10 therapies at $70 or less for all members in Silver, Gold, and Platinum plans

Conclusion

As an organization that prides itself in being "evidence-based" and "patient-centered" – values that we hope Avalere also aspires to – we take seriously the importance of framing policy issues in a balanced way. I provide these observations both to set the record straight and to provide Avalere the opportunity to update and correct its misleading analysis. In particular, what follow are recommendations and suggestions:

- Avalere should make publicly available the underlying data upon which its full report is based, so that others may analyze the data.

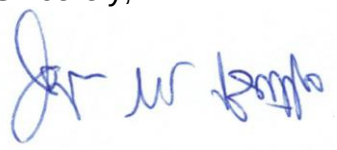
- Avalere should consider the comments made above and update its report on this important issue to fully reflect a balanced analysis of the potential experience of people with HIV/ADS in exchanges.

- Avalere should consider sharing drafts of reports with affected groups for comment, prior to distribution or publication. While Gilead Sciences – the largest producer of HIV/AIDS drugs in the nation – funded the analysis, Avalere notes that it maintained "editorial control" over the report. Avalere does not state whether its analysis, plans, drafts or methodologies were shared with Gilead and if their input informed how the analysis was conducted. Such input is not necessarily inappropriate, but it is seems striking to note that while Gilead may have been very involved, to my knowledge no individuals involved in exchanges were consulted to assure the analysis was sound and reflected current practices.

All Exchanges, including Covered California, take very seriously their obligation to provide affordable Essential Health Benefits to all enrollees. In particular, cost-sharing for Covered California enrollees has been examined and discussed thoroughly by our leadership, our Board of Directors and the stakeholder community – including HIV/AIDS advocates, health plans and clinicians. We have used "active purchasing" to maintain reasonable levels of cost-sharing while also succeeding in keeping premiums affordable, as shown by our low average 4.2% premium increase for 2015 and lower 4.0% premium increase for 2016. We look forward to continuing to have affordable products and consumer-friendly benefit design anchored in sound analysis.

We appreciate your consideration of these suggestions and comments.

Sincerely,



John M. Bertko
Chief Actuary

cc: Covered California Board of Directors

Attachments:
HIV/AIDS Drug Coverage for Covered California Plans: 2015 and 2016