Special Pharmaceutical Benefits Program Advisory Council
Thursday, October 28th, 2021
10:00 A.M. – 12:00 P.M.
Virtual Meeting

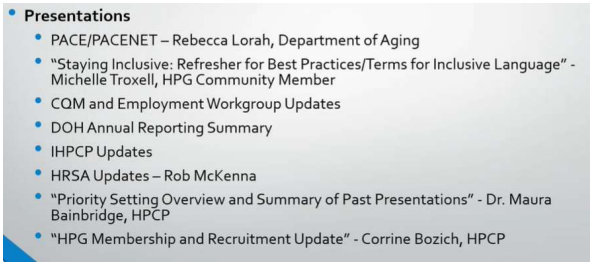
Topic/Discussion	Action
Introductions, Announcements & Updates: **John Haines**	Meeting commenced at 10:01am
Introductions: SPBP Advisory Council Members, staff, and guests introduced themselves. **Members Present:** John Haines, Margaret Hoffman-Terry, Angela Kapalko, David Koren, Deborah McMahon, Mimi McNichol, Meghan McNelly, Wayne Williams, Art Williams, Jerry Coleman, Michael Witmer, Cindy Magrini, Carina Havenstrite, Rob Pompa **Guests:** Casey Johnson, Mike Hellman, Anna Barone, Erica Freedman, Cindy Snyder, Kathryn Smith, Shana Colon, JP Burkhart, Francesca Wroten, Glen Young, Vanessa Zeilinger, Michael Latady, Jennifer Baumgardner, Brandon Anderson, Inger Taylor, James Forgrove, Deborah Murdoch, Michael Frederick, Morgan Curran **Department of Health Staff**: Lindsey Pitten, Kyle Fait, Monisola Malomo, Michelle Schlegelmilch, Erik McDowell, Moira Foster, Nnenna Ezekoye, Rob Smith **University of Pittsburgh Staff**: David Givens, Scott Arrowood	10:02am to 10:06am
Announcements/Updates John Haines • 2022 SPBP Advisory Council meeting dates will be last Thursdays of January, April, July and October. Next meeting is conference call 10am-Noon on January 27th. • New staff member who joined us in the last month: Nnenna Ezekoye, as a program analyst. New position that is evolving. • SPBP staffing customer services team remains the same. • Drug formulary was updated for the quarter as of October 1st on the website: www.health.pa.gov/SPBP • Notable update to the formulary is new generic HIV treatment medication that is available now (etravirine, for INTELENCE) A non-nucleoside reverse transcriptase inhibitor, or NRTIs. • Continuing with Medicaid back billing cycles; currently in the fourth cycle of Medicaid recoveries. It's done on quarterly basis and is satisfying the obligation from HRSA site visit. • Currently working on getting the updates for the Medicare Part C and Part D plan list for 2022. Open enrollment for Medicare is occurring, but also	10:07am to 10:38am

waiting for the Medicare plans to return their agreements to SPBP. This is to allow us to make premium payments like we do currently for 2021. Not expecting any major changes to plan lists for 2022, but still waiting for those official agreements to be signed and returned.

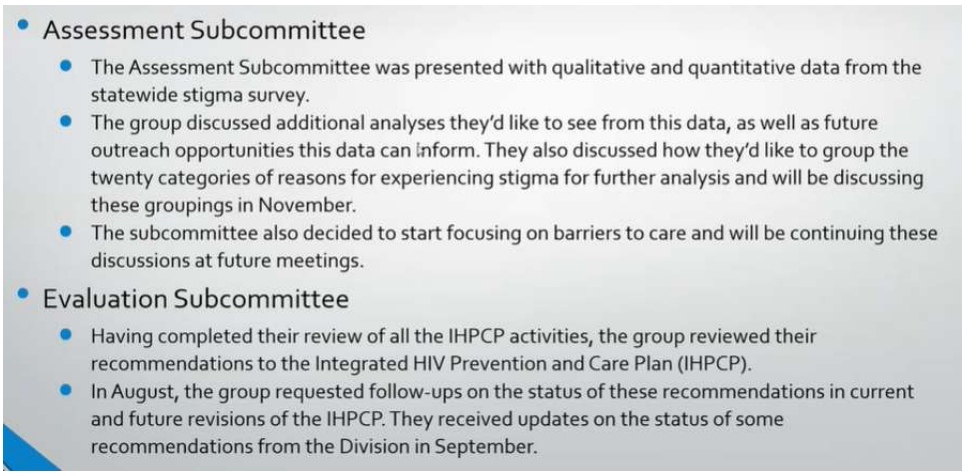
- Mailed out to the individuals who are eligible for auto enrollment into Medicare Part D plans; Likely received in mail 2 or 3 weeks ago.
- Updates to the customer service line: Now have 4 options to select to transfer to appropriate call center. Intent to expedite most appropriate team for calls; but anyone who waits on the line will also be directed.
- Policy notice released by HRSA: Allowing Ryan White programs to determine how often re certification is done for clients and removed the six-month requirement. We are moving to a one-year process where new clients would enroll in the program, complete what we call our full application and submit all the necessary documents. Feedback: one member stated they were on that HRSA call and supported the decision; additional supportive statements from 2 other members.
- Division has talked internally about aligning income criteria across all Ryan White, Part B, including SPBP and the Ryan White part be regional grantees and their sub recipients. Do not expect anyone to lose coverage based on the alignment of criteria. Flexibility is allowed is submitted household vs individual income.

David Givens

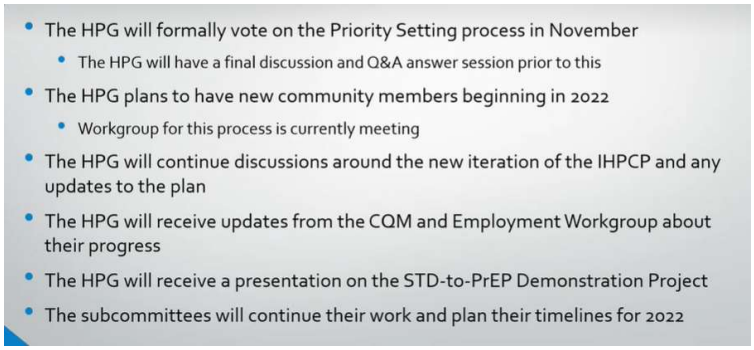
- HPG held 4 meetings since last SPBPAC: One 2-day in August; a one-day in September; and 2 information Q&A sessions between DOH and HPG members.



- Now through next year, focus is Integrated HIV Prevention and Care Plan. We are solidifying the draft of the integrated plan. All responsible parties for creating that plan have their assignments and are working.
- Subcommittees:



- Looking ahead:



- Recruitment: the packet to apply for HPG membership is on www.stophiv.com. Application can be online or print/mail.

Approval of previous meeting's minutes

- There is one outstanding question about whether Wayne needed to be added to the July minutes: John Haines will follow up. Otherwise, minutes were approved.

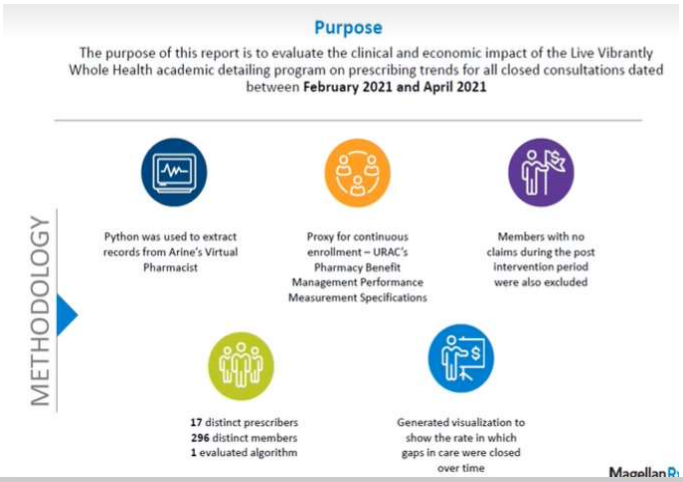
Minutes were approved 10:39am

Medication Adherence Pilot Program – Magellan Health

10:40am – 11:00am

Vanessa Zeilinger

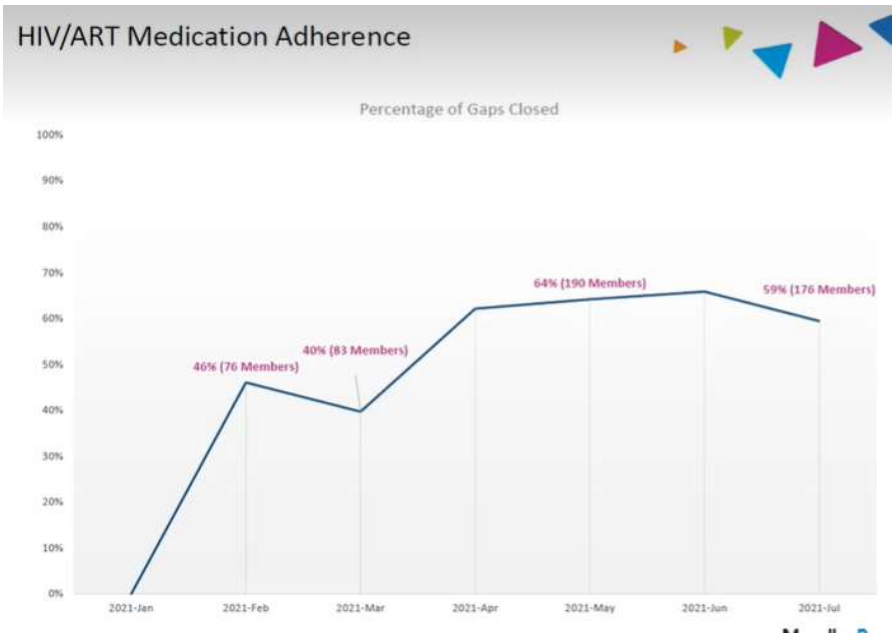
- **Whole Health Rx:** a pharmacist led prescriber facing product.



	Month of Outreach						Outreach Totals
	February 2021	March 2021	April 2021	May 2021	June 2021	July 2021	
Targeted Providers	10	7	5	4	5	-	31
Identified Client Opportunities	257	173	83	65	72	-	650
Faxed Letters	10	7	5	4	5	-	31
Closed Provider Consultations	4	4	4	5	3	2	22
# of Clients with Opportunities Addressed by Consultation	118	111	68	82	48	26	371
Clients Identified for Case Management by Pharmacist	6	2	1	2	1	-	12
Clients Identified for Case Management by Provider	-	-	-	-	-	-	-
Clients Enrolled in Case Management	-	-	-	3	1	-	4
Closed Follow-Up Consultations	-	-	-	3	5	5	13

- PDC – Proportion of Days Covered

HIV/ART Medication Adherence (n = 296)	
Proportion of Adherent Members (PDC ≥ 90%)	
Pre (%)	21.6%
Post (%)	63.9%
% Change in proportion adherent members	195.8%
Mean PDC	
Pre (SD)	77.2 (16.1)
Post (SD)	85.6 (20.6)
% Change in Mean PDC	10.9%

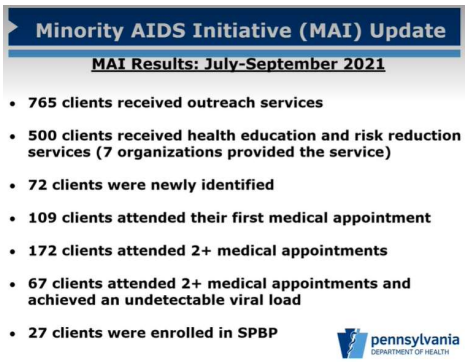


- Limitations: Unable to account for seasonality; Did not exclude members based on the specific places of service and/or diagnosis codes; and Small sample sizes and limited follow up period.
- Q&A
  - All participants were ADAP clients
  - How do we know if patient is taking meds or just getting auto refills on scripts? There isn't a perfect answer but using the PDC perhaps closed off some of those false positives. It was suggested to pull in viral load data, which would provide more insight.
  - One member said their patients are asked to bring in bottle have pills counted to support better estimate of adherence with their patients.

Outreach, Special Projects, and Minority AIDS Initiative Update — 11:00am to 11:21am

Kyle Fait

- This was a strong quarter, likely due to coming out of pandemic.



- MAI Provider spotlight: St. Christopher's Hospital for Children, a partnership of Tower Health and Drexel University. Have comprehensive care one day a week including primary, specialty and other things like PrEP. In first quarter had 101 clients received outreach; 46 of which received health education and risk reduction. 13 new clients; 14 removed because they were identified as linked to other providers. Typically have a high rate of undetectable viral loads (85%) but haven't been able to report that recently because of lack of access to lab work due to pandemic.
- PA NEDSS/PA-DORS – looking to go live on January 3, 2023 (a year extension from the original 2022 date). Working on data collection, site-minder authentication, training plans, cloud hosting.
- HIV Annual Conference: mini conference scheduled for Tuesday December 7th, 9-11:30am. Topics include telemedicine across the continuum. Still open to in-person conference in 2022 if possible.
- PAC systems upgrade. Magellan will be presenting a demo to the Division next month.
- SAF for localized media, innovation, and emergency preparedness: funds distributed to regions in July to implement localized media campaigns (traditional and social media). Targets: Spanish speaking PLWH in Hazelton; PrEP; wellness; stigma; expanding existing campaigns such as AIDS Free Pittsburgh. Just under $2 million awarded to three different regions.
- Anti-stigma campaign 2022-23. To be conducted by the University of Pittsburgh, who has experience with past anti-stigma campaigns.
- 5 Year Spend Plan Extension. The extension is expected to be granted for an additional 5 years. Currently a little less than half is spent and we are near the end of the original 5-year period.
- Next HPG meeting is November 17 and 18th; already reviewed earlier in the meeting with David Givens.

Clinical Quality Management Update — 11:21:am to 11:42am

Michelle Schlegalmilch

- CQM includes all Part B funded services, including an ADAP measure.

Performance Measures, 2021

Indicator	1st Quarter Review, 2021	2nd Quarter Review, 2021	3rd Quarter Review, 2021	4th Quarter Review, 2021
Outpatient Ambulatory Health Services				
HIV Viral Load Suppression	290/312, 93%	335/387, 87%		
Chlamydia Screening	179/539, 33%	291/482, 60%		
Syphilis Screening	315/539, 58%	380/482, 79%		
Hepatitis B Screening	43/539, 8%	61/482, 13%		
Hepatitis C Screening	207/539, 38%	192/482, 40%		
Annual Retention in Care	Not Available	324/387, 84%		
Medical Case Management				
Prescription of HIV Antiretroviral Therapy	800/3587, 24%	719/4399, 16%		
Annual Retention in care	Not Available	673/1116, 60%		
HIV Viral Load Suppression	353/389, 91%	1001/1116, 90%		
Food Bank/Home Delivered Meals				
HIV Viral Load Suppression	94/100, 94%	471/518, 91%		

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Performance Measures, 2021

Indicator	1st Quarter Review, 2021	2nd Quarter Review, 2021	3rd Quarter Review, 2021	4th Quarter Review, 2021
Housing Services				
Housing Status	6/94, 6%	20/124, 16%		
HIV Viral Load Suppression	5/7, 71%	17/18, 94%		
Health Education/Risk Reduction				
HIV Viral Load Suppression	3/4, 75%	129/142, 91%		
ADAP				
ADAP Application Determination Report Period: 4/1/20-3/31/21	251/252, 100%			

- Ryan White Part B CQM Quarterly reports include data collected from Rebates, Emerging Communities (EC), Minority AIDS Initiative (MAI) & Special Pharmacy Benefits Program (SPBP).
- The 1st Quarter 2021 report does not include data from Northwest Alliance-Clarion region & UPMC Presbyterian Shadyside (JHF region). The 1st Quarter 2021 data was updated 6/28/2021 to reflect the inclusion of The Wright Center (UWWV region). The 6/28/2021 update does not include any revisions to the viral load comparison data for CAREWare and surveillance data used for the CQM Workgroup focus on Medical Case Management, Viral Load Suppression.
- All Viral Load Suppression Performance Measure indicators were revised to reflect reference to "at least 1 medical visit" in the data parameter. A "medical visit" is defined as being "at least 1 Outpatient Ambulatory Health Service medical visit."
- "12-month calendar year" referenced in the CQM Plan has been revised to reflect "measurement year."
- For the 1st Quarter 2021 data a preceding 12-month viral load lookback for Medical Case Management clients in both CAREWare and surveillance data was used. Beginning in the 2nd Quarter 2021 data all Viral Load Performance Measure indicators will include a preceding 12-month lookback in CAREWare and surveillance to determine the most recent viral load test.
- The data parameters for the Retention in Care Performance Measure indicators (OAHS & MCM) were clarified to reflect the inclusion of a viral load test. Beginning 2nd quarter 2021, the Retention in Care Performance Measure indicator will include a preceding 12-month lookback in CAREWare.

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- Quality Improvement Project: purpose to evaluate effectiveness of Medical Case Management and the Viral Load Suppression. Workgroup has identified counter-measures to address problem areas, starting with the low-effort/high-impact areas to intervene. Recommendations distributed to regional grantees in September and to Providers in October 2021.

CQM Workgroup, Quality Improvement Project : MCM, Viral Load Suppression

1st Quarter 2021, RW Part B Data	2nd Quarter 2021, RW Part B Data
A total of 3,348 clients received MCM services 1/1/2021-3/31/2021.	A total of 4,399 clients received MCM services 4/1/2021-6/30/2021.
Of the 3,348 clients served 1,144 clients had a documented viral load in either CAREWare or surveillance during the preceding 12 months (34%).	Of the 4,399 clients served 1,116 clients had a documented viral load in either CAREWare or surveillance during the preceding 12 months (25%).
Of the 1,144 clients tested 1,026 had a HIV viral load <200 copies/mL, most recent VL test result used (90%).	Of the 1,116 clients tested 1,001 had a HIV viral load <200 copies/mL, most recent VL test result used (90%).

- Since last SPBPAC, distributed a CQM plan policy including requirements surrounding participation in the plan.
- Estimated 13,962 unique clients who received at least one Ryan White Part B service. SPBP had 6203 unique clients and in working with John Haines, identified a viral load performance measure for next year. Medical case management had 5119 unique clients. Foodbank at-home delivered meals had 2815 unique clients and retention and services. Performance measures identified for each of the above.
- Two additional overall performance measures included for next year's plan: Overall HIV viral load and Overall Newly-Diagnosed HIV.

c+e Collaborative, Combined Data

Provider	Performance Measure	Report Period	Outcomes Data
UPMC Presbyterian Shadyside (PACT) & Allies for Health and Wellbeing	Overall Viral Suppression Measure	2/1/2020-1/31/2021	1489/1745, 85.32%
		4/1/2020-3/31/2021	1507/1758, 85.72%
		6/1/2020-5/31/2021	1551/1761, 88.07%
		8/1/2020-7/31/2021	1584/1763, 89.84%
UPMC Presbyterian Shadyside (PACT) & Allies for Health and Wellbeing	Viral Suppression Age Measure, 40-64	2/1/2020-1/31/2021	933/1092, 85.43%
		4/1/2020-3/31/2021	935/1091, 85.70%
		6/1/2020-5/31/2021	967/1097, 88.14%
		8/1/2020-7/31/2021	978/1089, 89.80%

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- This year is the first year where viral load reporting will be mandatory for the whole year and is expected to better reflect actual viral load information.

Fiscal Update 11:43am to 11:46am

Erik McDowell

RW 2020

Funding	RW FY 2020
SPBP Grant Award	$26,832,592
Part B Grant Award	$10,648,813
Carry-over 2019	$6,574,999
Rebates	$72,705,436
TPLs	$3,864,449
State Appropriation	$0
Total Funding	$120,626,289

Expenditures	RW FY 2020
Drug Claims	$71,572,894
Claims Admin	$1,852,344
Medicare Claims (Parts C & D)	$0
RW Grant Admin	$4,703,074
RW Lab Testing	$257,346
Regional Expenditures	$5,525,094
Total Expenditures	$83,910,752

- There are approximately $35 million in commitments for 2020; which brings expenditures very close to full funding.

RW 2021

Funding	RW FY 2021
SPBP Grant Award	$26,372,453
Part B Grant Award	$10,454,210
Carry-over 2020	$7,757,799
Rebates	$79,259,402
TPLs	$4,962,956
State Appropriation	$0
Total Funding	$128,806,820

Expenditures	RW FY 2021
Drug Claims	$9,027,153
Claims Admin	$504,944
Medicare Claims (Parts C & D)	$163,473
RW Grant Admin	$2,544,377
RW Lab Testing	$73,063
Regional Expenditures	$6,939,595
Total Expenditures	$19,252,606

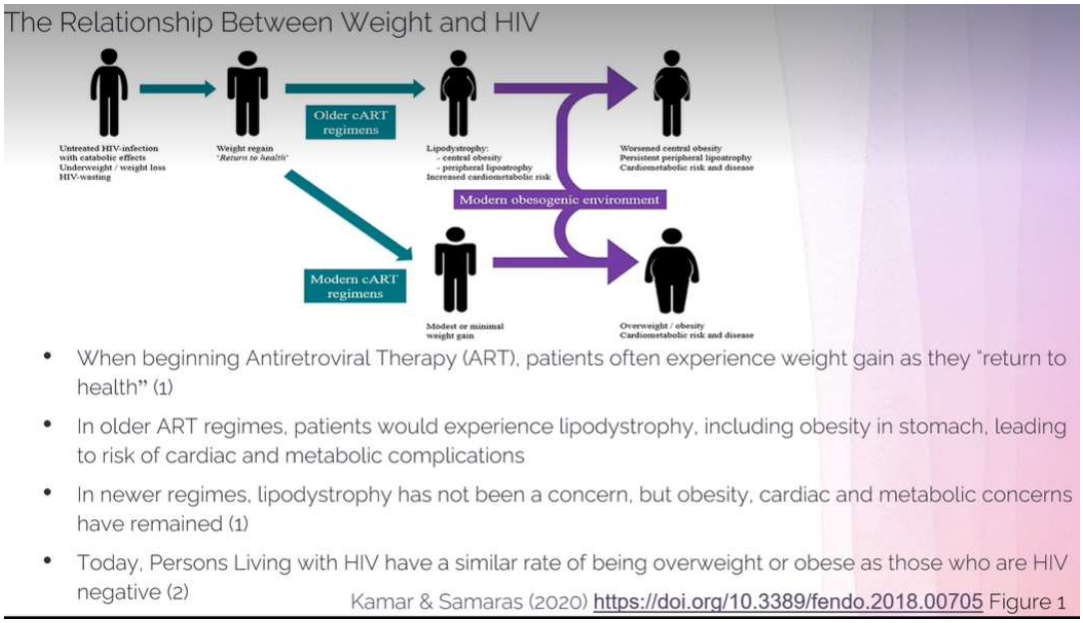
- 2020 carry-over into 2021 approved.

New Drug Additions and Exclusions

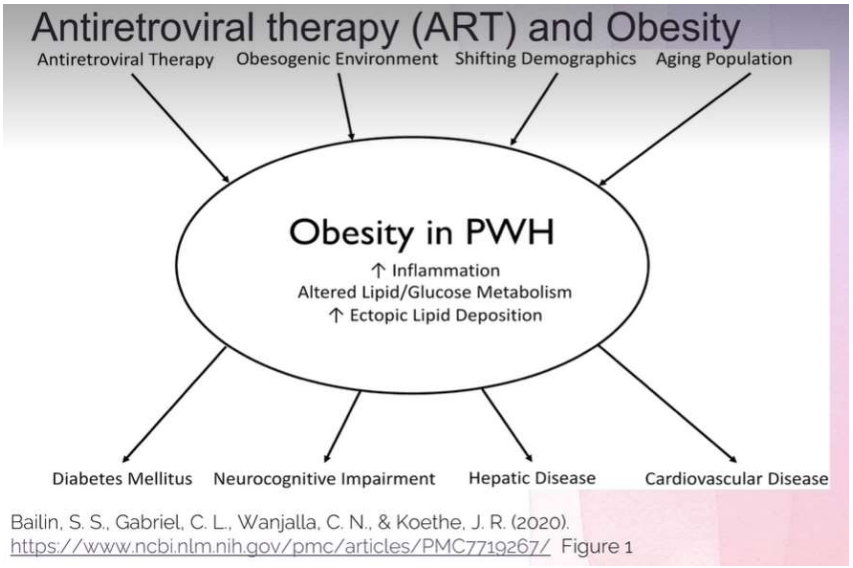
Margaret Hoffman-Terry

- New recommendations for additions: many seem to be antineoplastics; some antibiotics for unusual infections; one anticonvulsant; cancer drugs; contraceptives; new type of insulin with auto injector. They are in classes typically covered. Are they any questions about specific agents on the list? None
- Exclusions lists: inpatient antimalarial drug; off-label covid drug that is not on FDA-approved. No questions from group.
- Motion made to accept Additions and Exclusions. Seconded by Deborah McMahon. Passed unanimously.

Michael Witmer and Francesca Wroten – Presentation on Medical Necessity for Weight Loss Medications in HIV Patients.



- Rates of obesity of those with HIV are about the same as general population.



11:47am to 12:08pm

Antiretroviral therapy (ART) and Obesity

The combination of antiretroviral therapy (ART) and the following weight-gain characteristics of HIV patients:

- Obesogenic environment that involves a high fat diet and low activity (as we see across the U.S.) (3)
- The aging population (a majority of our patients are at this stage of life) that is predisposed to weight gain naturally
- Shifting demographics

Can contribute to the following metabolic complications:

- Diabetes
- Neurocognitive impairment (every day impact on learning, remembering concentrating
- Hepatic (liver)disease
- Cardiovascular disease (3)

Impact of Obesity on PLWH

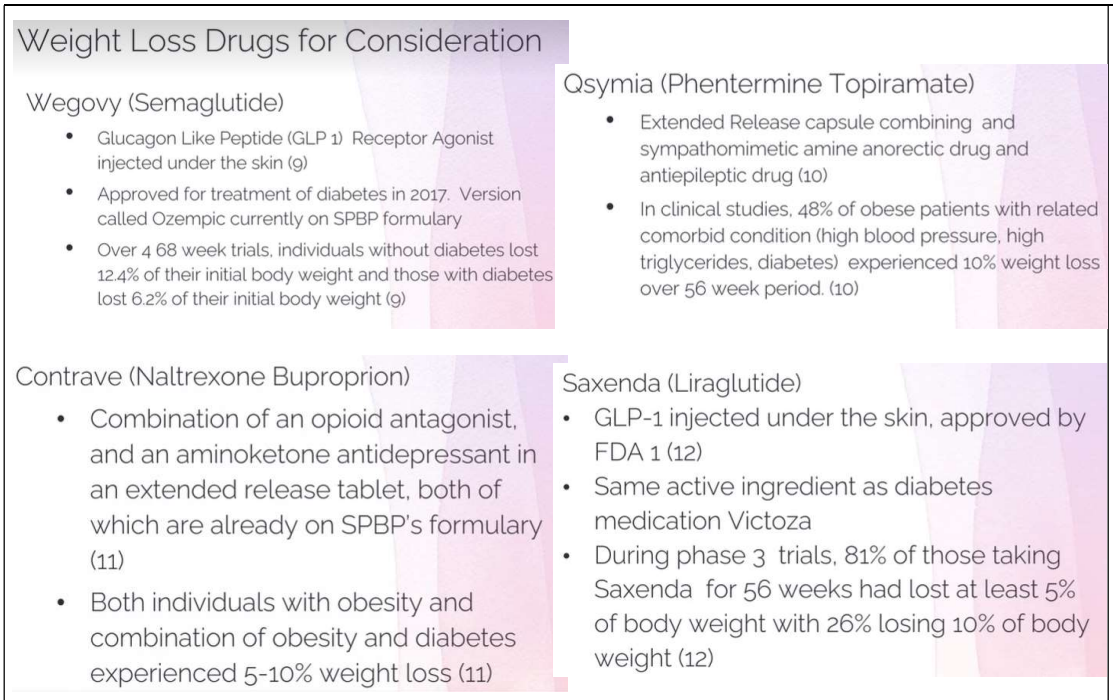
- 1 in 5 men and 2 in 5 women living with HIV are obese (2)
- Recent studies have reported that one in six people starting HIV treatment gain at least 10% in body weight over one to two years of starting ART (4)
- According to the Veteran Aging Cohort Study, for every 5 lbs a PLWH gains, their risk of diabetes increases 14%, in the control group the increase was only 8% (5)
- A meta-analysis of articles on diabetes in persons living with HIV found that within 3.7 years of starting ART, 13.7% will develop diabetes (6).
- Accoding to a meta analysis of HIV and cardiovascular disease, PLWH are twice as likely to experience cardio vascular disease as someone who is HIV negative (7)
- Studies also show that people with more advanced HIV (low CD4 counts, high viral load) gain more weight, as do people who were underweight before starting treatment (4)
- One explanation is that weight gain is a result of immune recovery. Long-term viral infection depletes fat stores. When people recover from famine or severe infection, body fat stores are replenished (4).

Integrase + TAF

- As seen in the previous diagram, weight gain is common with antiretroviral therapies and can lead to significant medical complications for PLWH (3,8)
- Some antiretroviral regimens (medications) contain an integrase inhibitors (stop the virus from multiplying) and tenofovir alafenamide (TAF) a nucleotide reverse transcriptase inhibitor - these medications are associated with a great deal of weight gain (8)
- Another theory is that integrase inhibitors might cause weight gain through effects on the hormonal system which governs appetite regulation, leading to increased food intake (4)
- Due to their effectiveness, medications containing Integrase and TAF such as Biktarvy and Genvoya are among SPBP's most popular
- **Why is this a problem?:** We want our patients to have the most efficient medication options possible, but we don't want to put them at risk for more medical complications as a result.

What to do about this?

- In patients who are overweight, even losing 5% to 10% of body weight can reduce risk of cardiovascular disease (9)
- Although more research is needed regarding prevention and treatment of obesity for people living with HIV we have some existing tools to help treat patients including nutritional counselling, exercise and surgical weight loss treatment (1)
- Medications are another available tool for treating obesity, but they have been excluded from the SPBP formulary in the past due to being considered cosmetic in nature.
- Based on what we now know, we believe that determination should be revisited
- There are currently four FDA approved drugs for the medical management of obesity. We are requesting they be added to the SPBP formulary



- Putting weight loss drugs on SPBP formulary is another tool.
- Several comments expressing gratitude for presentation.
- Noted that weight data is not collected currently, but it may not be necessary. Though data may be helpful in demonstrating the usefulness of a state ADAP program adding these to their formulary, where many states do not. Motion made by Margaret to add (and remove language of exclusion); seconded by Angela; passed unanimously.

No other subcommittee updates or final comments Next meeting is January 27, 2022. Virtual at 10am.	12:09pm
Adjournment	John Haines adjourned the meeting at 12:10pm