



Welcome to:

Striking Back Against the Rise of Diabetes During COVID-19

Note: You should hear music playing right now!

If not, please adjust your audio settings. **Our program will begin at 8:00 am!**



Agenda (approximate timing)

8:00 – 8:30	Current State of Diabetes in the COVID-19 era. Melissa Brewster , PharmD, BCPS – CareOregon
8:30 – 9:30	Managing Diabetes with complex co-morbid conditions. Dr. Leonard Bertheau , DO – Adventist Health
9:30 – 10:00	Q&A with Dr. Bertheau
10:00 – 11:00	Navigating medications and CareOregon’s treatment pathway. Cory Bradley , PharmD – CareOregon
11:00 – 11:45	Q&A with Melissa and Cory .



Core Learning Objectives

- Understanding of how COVID-19 has increased diabetes death rates and how people with diabetes are more likely to have serious adverse complications from COVID-19 (**Melissa Brewster**, PharmD, BCPS – Senior Pharmacy Clinical Coordinator, CareOregon)
- Improving diabetic management with a review of medication classes including newer agents and insulin (**Dr. Leonard Bertheau**, DO – Diabetes and Endocrine Center, Adventist Health)
- CareOregon’s Diabetes Treatment Pathway and best practices for how to use the pharmacy benefit effectively (**Cory Bradley**, PharmD – Pharmacy Operations Manager, CareOregon)



Survey Completion for 3.25 Hours CME Credit:

Program must be viewed in its entirety.

Upon completion, email carsonp@careoregon.org for assessment survey, indicating the type of credits needed – thank you!

American Academy of Family Physicians – Prescribed credit, American Medical Association (AMA) Physician’s Recognition Award (PRA) Category 1 Credits 3.25 hours	Oregon Board of Pharmacy – Recognizes credits to toward CE hours requirements for license renewal! 3.25 hours	<u>NEW</u>: National Association of Social Workers – LCSW CEU credits 3.25 hours
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Join Our Upcoming Session:

Culture and Illness –

Implications for Clinicians and Related Health Professionals

– December 9th <https://bit.ly/3tRdeCL>

Past sessions on video: <http://www.careoregon.org/medsed>



Panel Questions & Answers

Submit questions via Chat feature:

For Melissa: *“How do you...”*



When the Tornado Hit Kansas: The Impact of COVID-19 on Diabetes Treatment

Melissa Brewster, PharmD, BCPS –
Senior Pharmacy Clinical Coordinator
CareOregon



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Objectives

- Understand the impact of COVID-19 on clinicians
- Describe how chronic disease management has changed during the pandemic
- Discuss ongoing challenges and opportunities for diabetes management



An Acknowledgement

“ [Daring greatly] means the courage to be vulnerable. It means to show up and be seen. To ask for what you need. To talk about how you're feeling. To have the hard conversations.”

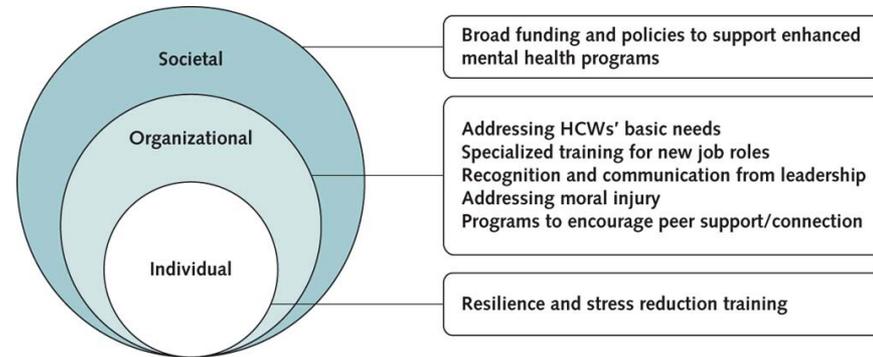
— BRENÉ BROWN, PHD, LMSW

SUPER
SOUL
sunday



A Few Wellness Pointers

- Care for Clinician basic needs
- Clear communication from leadership
- Resilience and stress-reduction training
- Acknowledging the moral injury and impact of patients on wellness
- Social and peer support
- Normalizing and knowing when to access Mental Health care



The Challenges of COVID-19 in Chronic Disease

- Current effects of COVID-19 on those with, or at risk for, chronic diseases and those at higher risk for severe COVID-19 illness
- Post-pandemic impact of COVID-19 on the prevention, identification, and management of chronic disease
 - Decreases in preventative and diseases management care, reduction in ED use
 - 4 in 10 adults report delaying or avoiding care
 - Decreased cancer screenings and identification predicted to result in almost 10,000 preventable deaths
 - Lost ground in pediatric immunization, mental health, and substance abuse
- Long-term COVID-19 sequelae, both as a disease entity and from a population perspective



Hacker et al. Prev Chronic Dis 2021

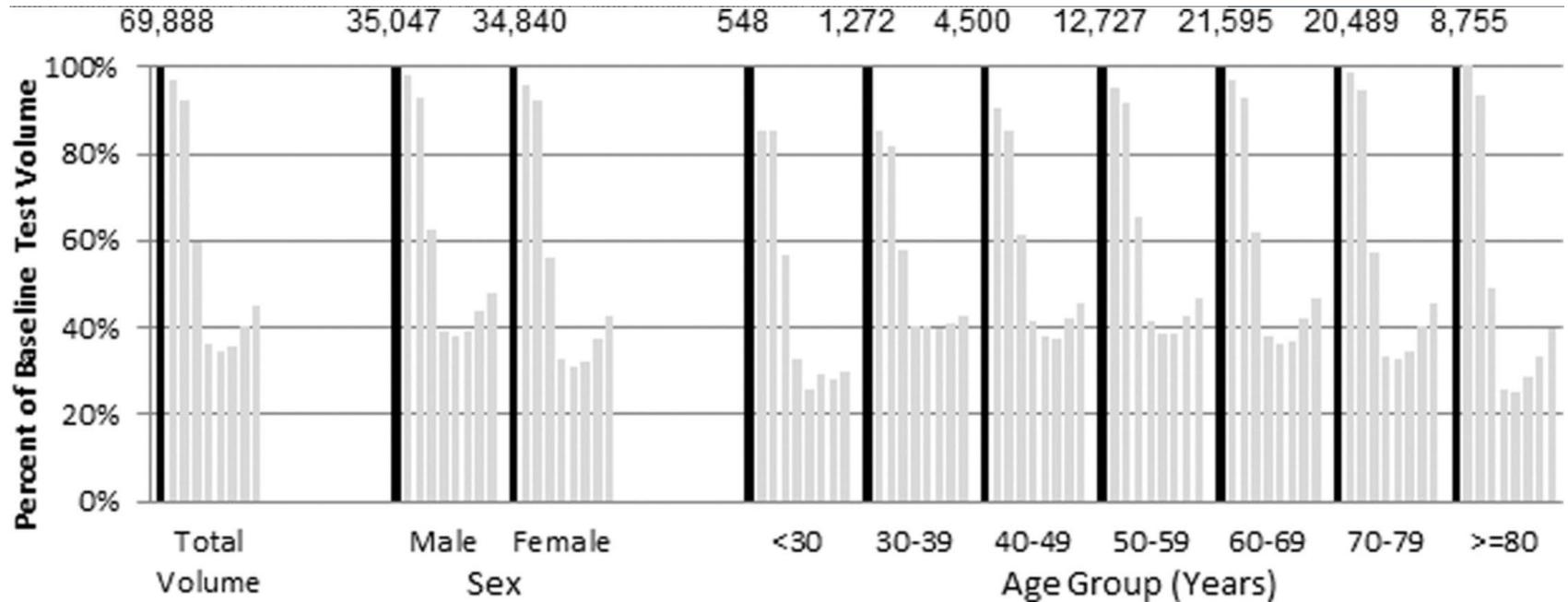


Assessing Impact

- What diseases have been missed or allowed to worsen?
- What is the status of prevention and disease management efforts?
- Have prevention and disease management efforts been affected by concerns such as job loss, loss of insurance, lack of access to healthy food, or loss of places and opportunities to be physically active?
- How have effects of the pandemic on health care systems (staff reductions, health practice closures, disrupted services) away from ongoing chronic disease prevention efforts been experienced?

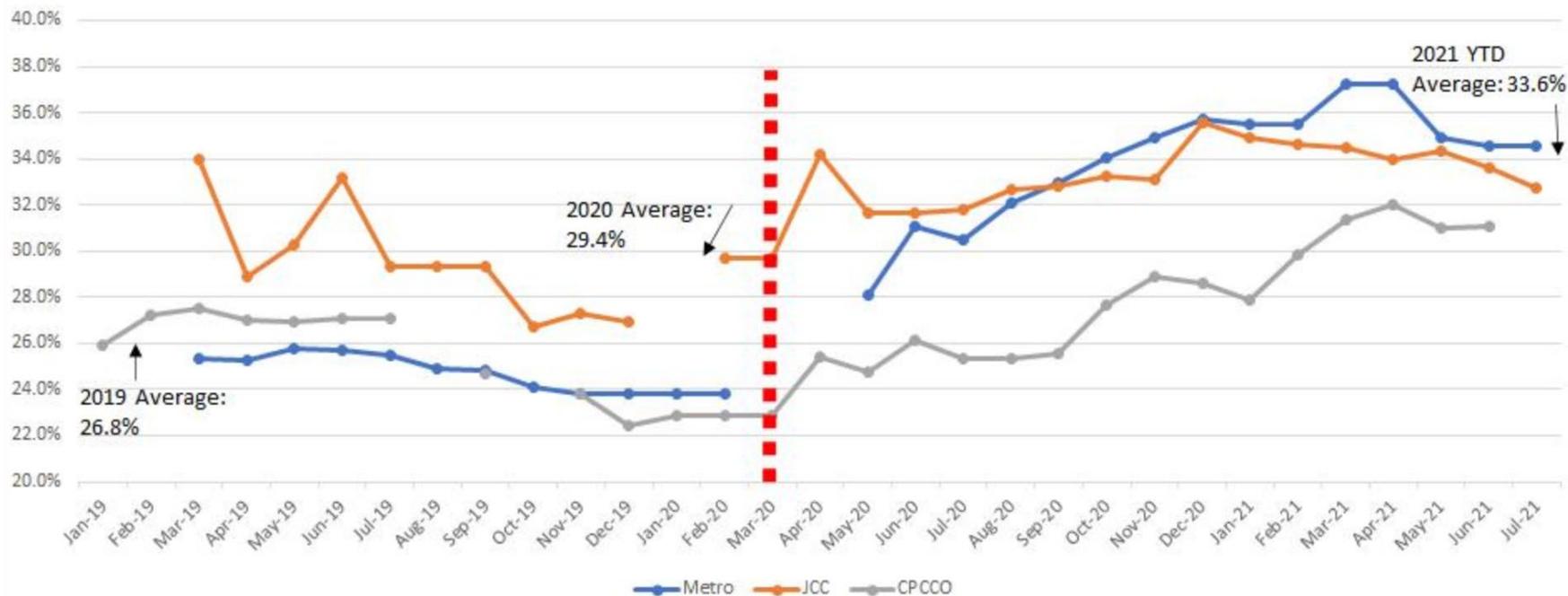


Diabetes Monitoring During COVID



Diabetes – What Are We Seeing?

Diabetes A1c Poor Control Rates 2019-2021 YTD



Diabetes – What Are We Seeing?

Rates of complications among adults with severe COVID-19 infection

	HbA1c \geq 6.5%	HbA1c $<$ 6.5%
Secondary respiratory infection	89%	67%
Acute respiratory distress syndrome	61%	29%
Critical illness	68%	37%
Death	46%	22%



A Coming Wave?

Data still emerging on whether COVID-19 causes DM

- SARS-Covid-19 virus attach to and enter the pancreatic β -cells, killing some and reprogramming others
- In one Italian study, 46% of COVID-19 patients admitted had *new onset* hyperglycemia. For 35% of those patients, the hyperglycemia lasted 6 months or longer.
- Sitagliptan, a DPP-4, has shown promise in reducing mortality in patients with diabetes and COVID-19 by preventing the virus from entering cells

Montefuscu et al. Nature Metab 2021.

Solerte et al. Diab Care 2020.



Taking Steps Back Into Care

1. Raise Awareness

- Allay patient fears about returning to care
- Reemphasize importance of preventative and chronic disease management
- Explain safety and mitigation efforts
- Assist patients in gaining more confidence around COVID-19 vaccines
- Gain an understanding of how COVID-19 has disproportionately affected communities in your area- and take steps to reduce those disparities



Taking Steps Back Into Care

2. Collaborate on Solutions and Build Trust



- Public health plays a significant role in addressing health behaviors (healthy eating, physical activity, avoiding tobacco and other substance use) and community solutions to address SDoH that impact prevention and control of chronic disease
- Coalitions and community groups are critical change agents
- Solutions must also include direct discussions with residents in affected communities
- Conversations need to be bidirectional, long-term, and conducted by people who are trusted, who are respectful, and who can identify with affected populations



Taking Steps Back Into Care

3. Innovate

- Leveraging technology to expand the reach of health care and health promotion (eg, telemedicine, virtual program delivery, mobile device applications)
- Providing more services in community settings, as is increasingly modeled in the National Diabetes Prevention Program
- Using community health workers to assist in connecting to community resources
- Further enhancing approaches to increase access to and convenience of services (eg, home screenings) or monitoring (eg, home blood pressure monitoring)
- Watch out for magnifying existing disparities with technology



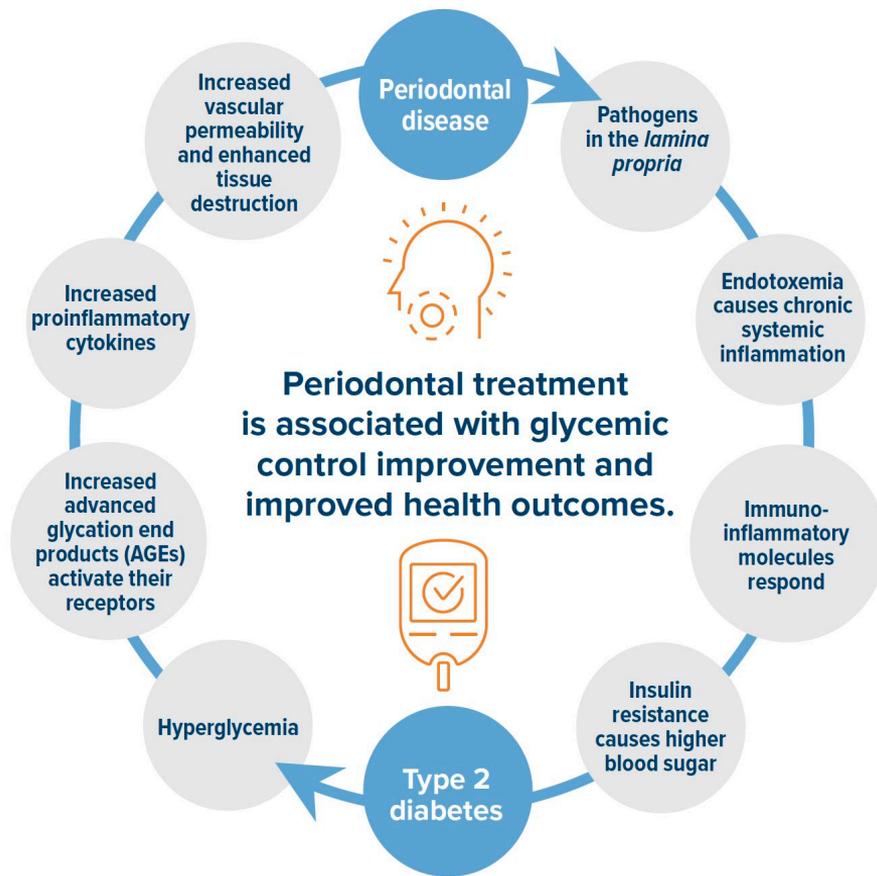
Taking Steps Back Into Care

4. Address long-term COVID sequelae

- Follow the research
- Listen to patients about ongoing symptoms
- Look into associations between long-COVID and Chronic Fatigue Syndrome, showing to be very similar conditions and possibly mechanisms



Dental Care in Diabetes



Five Ways to Increase Dental Care in Diabetes

1. Patient Access

- Identify common barriers to why patients with diabetes may not be able to access dental care.

2. Patient Education

- How do patients know if they have coverage for dental care? And why is dental care important?

3. Build bridges between dental clinics and primary care

- Use the CareOregon Dental Portal to get patients scheduled

4. Utilize common resources for integration

- Share methods across teams and organizations: use common platforms, EHRs, tracking/registries, staff and patient messaging.

5. Increase collaboration pathways

- Can you find a way to close the loop on referrals?



Summary

1. Thank you for your ongoing dedication to patient care in very disheartening times.
2. Take care of yourselves and your well-being. Take space, breaks, and ASK your leadership to assist with basic needs (food and breaks), communication, and training.
3. Assess the impact of delaying chronic disease care in your clinic- ask your CCO for data on your performance and for help with quality improvement efforts.
4. Allay patient fears about returning to clinic and collaborate with community organizations who can support SDoH.
5. Continue innovations like telemedicine and assist patients with getting access to telephones (ask CCO for assistance if needed).
6. Continue to monitor for long-term issues from COVID-19. Follow the literature. Take patients seriously. Treat symptoms.
7. Get patients with diabetes in for dental exams- likely the most neglected service during the pandemic.



Thank you!



Behind the Curtain: Improving Diabetic Management – New Agents and Insulin

Dr. Leonard Bertheau, DO

Diabetes and Endocrine Center –
Adventist Health



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CareOregon Diabetes Treatment Pathway

Preferred Oral Agents

1st line- Metformin
2nd line- Sulfonylurea or
Pioglitazone

Non-Preferred Oral Agents *PA Required

3rd line- DPP-4: Alogliptin or
SGLT-2: Steglatro or
Farxiga for HF,
ASCVD, CKD

PA Criteria:
1) Failure of metformin
2) Failure of SU or pioglitazone
3) A1c 7-10%

- If not at goal in 3 months, proceed to additional therapy.

- Review for treatment barriers before adding therapy: adherence, behavioral health and social determinants.

- Consider frequent follow-up visits to improve patient engagement and treatment success. Have patients engage with Behavioral Health coordinators and/or Clinical Pharmacists.

Preferred Injections

4th line- Basal insulin: Basaglar or Semglee or NPH
Consider adding Meal-time insulin: Admelog Pen

Non-preferred Injections *PA Required

5th line- GLP-1 agonist: Bydureon or
Byetta or
Trulicity or
Victoza

PA Criteria:
1) Failure of metformin
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All patients should receive diabetes education

Initial Therapy

- Metformin
 - Gold standard
 - Why we should use it
 - Durability
 - A1c reduction range
 - Dosing guidelines
 - What about CKD?



Initial Therapy

- Sulfonylurea
 - Why we should use it
 - Dosing guidelines
 - What to watch out for



Initial Therapy

- TZD (thiazolidinediones)
 - Why we use it
 - When we use it
 - What to watch out for
- Then what? How do you decide?
 - Factors to consider



Add-On Therapy: Newer Agents

- Factors to Consider
 - Concomitant chronic disease
- Choices:
 - Oral: DPP-4 Inhibitors and SGLT-2 Inhibitors
 - Why we use it
 - When we use it
 - What to watch out for
 - Factors to consider



DPP-4 Inhibitors: Alogliptin

- Why we use it
 - MOA
 - A1c effect
- When we use it
- What to watch out for



SGLT-2 Inhibitors: Steglatro and Farxiga

- Why we use it
 - MOA
 - A1c effect
- When we use it
- What to watch out for



When to Consider Basal Insulin



Choosing Insulin

- Basal insulin (Basaglar, Semglee, NPH)
 - What dose?
 - What time of day?
 - When to test?
- Bolus insulin (Admelog)
 - When to add?
 - When to test?
- Basal: Bolus ratio = 50:50



When Basal Alone Is Not Enough

When A1C is >2% above target

When A1C values are still not at target on basal

AND...

- Fasting BG* levels at or approaching target
- Post-prandial BG values remain above target

OR...

- Total basal insulin dose exceeds 0.5 units per Kg/day

Options:

- **Advance insulin therapy** with additional prandial insulin
 - Basal bolus insulin regimen
 - Premixed insulin
- **Add GLP-1 agonist therapy** if tolerated, not contraindicated and is affordable for the patient

*BG = blood glucose. American Diabetes Association. Diabetes Care. 2015;38(suppl 1):S41-S48.



Pros and Cons of 70/30

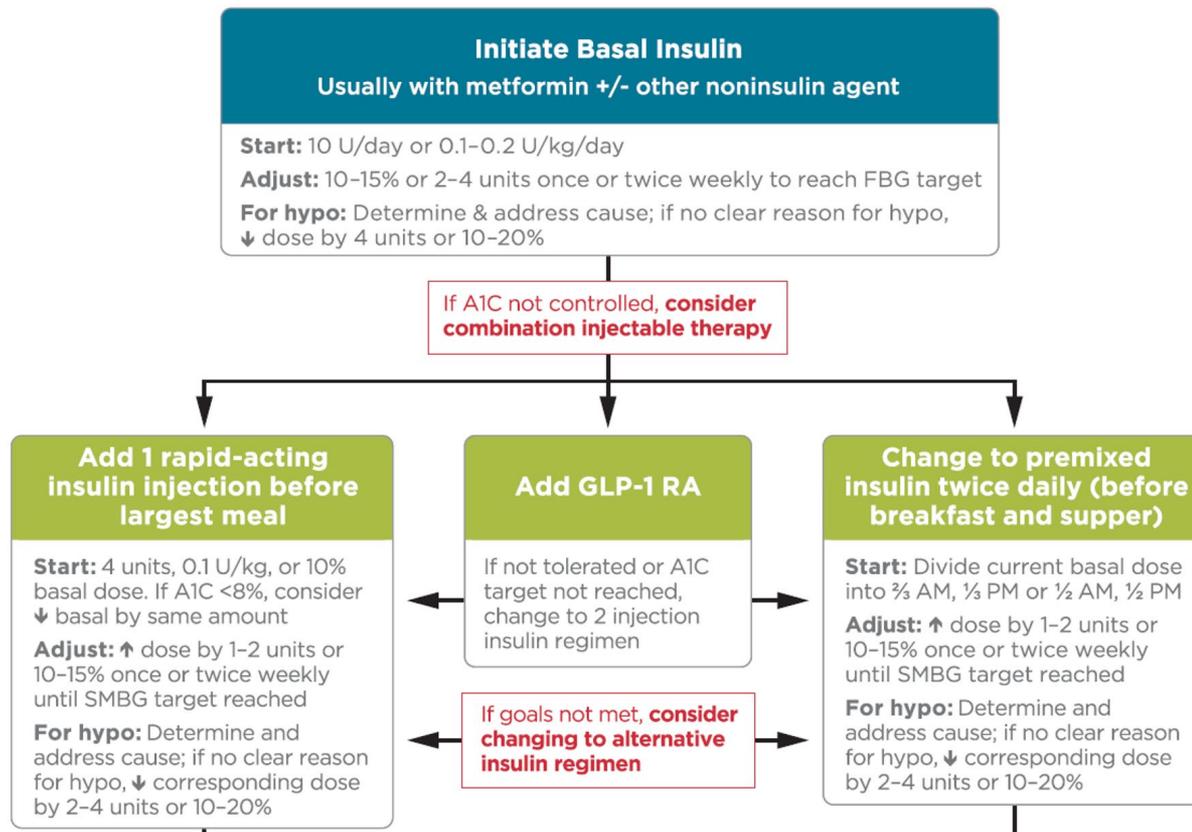
Pros	Cons
Basal and prandial coverage	70:30 ratio vs. 50:50
Less injections per day	Less flexible with dose adjustments
Less confusion on units to inject	Requires patient to eat consistently (time and carbs)
One insulin vial – may be more realistic option for patients with unstable housing or no place to store	



What About Insulin Resistance?



Insulin Therapy in Type 2 Diabetes



When to Consider a GLP-1 Agonist

- Why we use it
 - MOA
 - A1c effect
- When we use it
 - Combos that make sense
 - Added to basal insulin
 - Should I add prandial insulin or GLP-1?
- What to watch out for



When to Refer

- New onset DM2 with A1c > 12%
- Uncontrolled DM2 on basal/bolus insulin
- Gestational diabetes
- DM1
- Insulin pumps
 - Note that pump manufacturers can address pump malfunctions



Case Study

- 32 yo female, 425 pounds, 5 ft 10 inches.
- She was on metformin 1000 mg BID and Actos 45 mg daily.
- Her A1c was **7.1%**.

- I placed her on Byetta, first 5 mcg prior to breakfast and dinner, then 10 mcg prior to breakfast and dinner.
- 3 months later, she had dropped down to 388 pounds!!!!
- ...and her A1c dropped down to **6.4%**.

- 12 years later:
- She was only on Ozempic (she is no longer taking metformin due to diarrhea and Actos due to swelling and weight gain).
- She is down to 331 pounds and her A1c is **6.2%**.



Nutrition

- Does it make sense to carb count for type 2?
- What nutritional strategies or diets that are particularly effective?
- If you can convince a patient to make one change, what would it be? (asking patients to commit to switching to water, for example)



Physical Activity

- Time of day (people with diabetes should not exercise fasted or first thing in the morning, an after-dinner walk has huge benefits in managing glucose)
- A1c lowering potential?



Glucose Monitoring

- Is CGM ideal? For which patients?
(CGM is a DME benefit w/DME criteria – not a pharmacy benefit)
- How much monitoring is necessary for patients on orals and GLP-1s only?



Engagement Strategies

- With COVID-19's impact on chronic disease management, re-engaging with patients in their care is crucial
- Best ways to get patients invested in care
- Med adherence strategies
- Programs to support people with diabetes (local support groups, healthy nutrition programs, etc.)



CareOregon Diabetes Treatment Pathway

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Treatment Pathway Changes

- Highlighted additional SGLT-2 indications
 - Farxiga for CHF, CKD, ASCVD
- Removed A1c levels and simplified to preferred and non-preferred options
- Provided PA criteria



Thank you!



Dr. Bertheau Questions & Answers

Questions submitted via Chat feature



35 Break

5 minutes



Getting to Oz: The Yellow Brick Road of the Treatment Pathway

Cory Bradley, PharmD –
Pharmacy Operations Manager
CareOregon



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Learning Objective & Outline

CareOregon's Diabetes Treatment Pathway and best practices for how to use the pharmacy benefit effectively

- Go behind the scenes of formulary management
- Formulary 101: Rebates and Tiers
- Understand the changing costs of diabetes meds
- Common pain points
- Get best practice tips



Managed Care 101 and CareOregon



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CareOregon's Formulary Process

- All internal reviews and recommendations – CO-employed Registered Pharmacists – (RPhs)
 - All live locally
- Pharmacy & Therapeutics Committee
 - MDs and RPhs/PharmDs
 - Internal and external (majority external)
 - External representation from all 3 CCO geographic areas we serve



Whose Formulary Are We Responsible For?

- OHA Fee For Service/Open Card – **Nope**
- Columbia Pacific CCO – **Yep**
- Jackson Care Connect – **Definitely**
- Health Share of Oregon – **It's complicated**
 - Different entities within HSO, CareOregon is the largest.



Why Aren't Formularies Aligned?

Formularies
Formularies

- 90%+ alignment in most formularies
- Differences largely originate from different brand prices (rebates)
- Autonomy vs Political Pressures vs Part of Larger Systems/Companies



What's the Deal with Rebates?

- Rebates are a discount offered by the manufacturer to incentivize coverage.
- Historical minimal supplemental rebates for Medicaid at CareOregon.
- Larger player for Medicare and Commercial formularies.



“Why Does CareOregon PA So Much?”

- >99% of our claims don't require PA
- Only real cost containment tools
- Minimal rebates
- No co-pays
 - Commercial insurances and some Medicare plans can rely on high copays to incentivize members to use certain products instead of using the PA platform.
- Non-profit=> money saved goes back directly to other services and allowing more Medicaid coverage.



Diabetes Drug Costs



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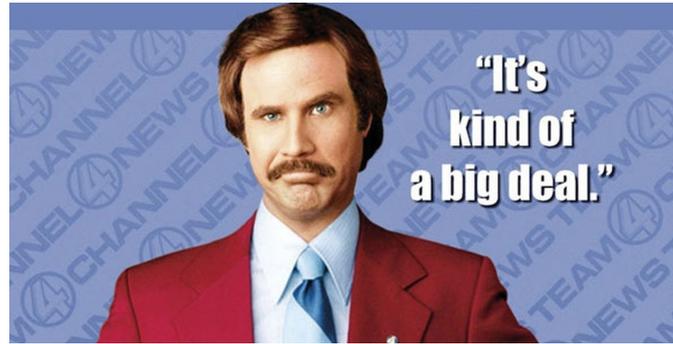


Diabetes Costs Per Month

- Metformin: \$4
- Watch out for certain ER formulations
- SUs: \$4-11
- Pioglitazone: \$10
- Alogliptin: \$200
- SGLTs: \$300-\$525
- GLP1s: \$800-\$1,000



In the Media



- “Insulin prices are out of control!”
 - Was true, but that has changed
 - A canary in the coal mine
- Rising drug costs are a factor every where and only getting worse
 - Gas station-esque PHRMA promised pricing (9.99%)

Insulin Costs – per 15 mLs pack

	OG Brands	Competition
Basal	\$430 (Lantus)	\$150 (Semglee = insulin glargine)
Mealttime	\$563 (Novolog/Humalog)	\$255 (Admelog)
Mixes	\$563 (Novolog 70/30)	\$282 (generic Novolog)



Cost Trends

	First Approved	Now
Humalog (10 mL vial)	\$61 (2002)	\$343 (462% increase in 19 years)
Lantus (10 mL vial)	\$51 (2004)	\$286 (461% increase in 17 years)
Farxiga	\$314 (2014)	\$537 (71% increase in 6 years)
Victoza (9 mL)	\$364 (2010)	\$1,025 (182% increase in 11 years)



Diabetes Treatment Pathway 2021



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All patients should receive diabetes education

What Hasn't Changed?

- General step-wise approach
- Sequence of therapies and preferred agents for MOST patients



What Has Changed?

- A1c reference removed
 - Confusion on starting place; PA criteria implications
 - Broader range allowed by criteria now (7-10%)
- Clearer identification of criteria details when applicable.
- Call out Farxiga allowance (vs Steglatro) for unique indications
- Enhanced clarity on GLP1s place
- Removed meal-time and GLP1 restriction



Continuous Glucose Monitoring

- Medical/DME benefit (not a pharmacy benefit)
 - Medicare may allow claims to process as Part B via a pharmacy.
- Authorization is required
- Medicaid Criteria (summarized from HERC):
 - Only for type 1 diabetes; **AND**
 - Documentation of education provided to member; **AND**
 - A) Insulin pump; OR B) A1c $\geq 8\%$ or frequent/severe hypoglycemia or impaired awareness of hypoglycemia; OR C) Pregnant woman (regardless of A1c level); OR D) Age < 21
- Renewal:
 - Have used the device at least 50% of the time at their first follow-up visit
- Medicare Criteria (from CMS) differences:
 - Type 1 or 2 diabetes; intensive insulin (3+ injections per day or pump); requiring frequent adjustment of insulin



Assessing Value



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Guidelines vs Practical Realities

- Tensions form when health plans need to address value/cost when guidelines almost never do
- Broad guidelines with multiple options
 - Is a section for “When cost is a factor”
- Recency/brand bias- PHRMA funding, drug reps.
 - No pioglitazone drug reps
- Critical scrutiny – studied populations vs intended population



Assessing Value – Cost to Avoid Event

- Victoza “13% lower rate of total CV event”=> 1.9% absolute lower=> NNT 53 patients for one CV event over 3.5 years.
- 53 patients x \$12,000 per year x 3.5 years = \$2,226,000 drug costs per avoided cardiac event
- Pathway is our attempt to balance a cost-effective approach but improve the health of our members.

Stats from Victoza FDA label published 11/20/20 via the LEADER Trial



If SGLT2s and GLP1s Were Second-Line in Pathway

- 2,000 members actively on an SU
- If this is a proxy for second line use, full conversion annual costs:
 - SGLTs2
 - Steglatro (4,000 Rxs per quarter x \$370- \$10) x 4 quarters = \$5.76 million
 - Farxiga 4,000 Rxs per quarter x \$600- \$10 x 4 quarters = \$9.44 million
 - Trulicity 4,000 Rxs per quarter x 910-10 x 4 quarters = \$14.4 million
- Total diabetes spend is ~\$19 million now.



PA Best Practice Tips



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Common Pain Points

- High A1cs, no insulin
 - A1cs above 10% ask for basal + mealtime insulin evaluation
 - Best chance at control
 - Not a hard cap, just need evaluation and reason
 - Require on all PA DM, and renewals.
- Failed or not failed?
 - Stated failures are clinically reviewed by our team
 - Adherence?
 - Alt options (metformin IR vs ER)
- Contraindicated
 - Is it though?
 - Clearly communicate patient risks
- Non-preferred SGLT2s
 - Steglatro first; Farxiga second (or if compelling indication)



PA Best Practices

- Criteria fully posted online
 - ePA in 2022
- Formulary fully posted online
- Stick to the pathway if you can, explain when you can't
 - Patient specific arguments, not form letters
- Submit documentation
 - A1cs in particular



Case Study Continued

- 32 yo female, 425 pounds, A1c is 7.1%, on metformin and pioglitazone
- What would the pathway ask for?
- What arguments might the provider emphasize for an exception?
- If approved, what information/documentation to submit on renewal?



What Can You Do?

- PCSK9 example
- Throw some water at that witch!



Thanks!
Stick around for the
Q&A Session!



Panel Questions & Answers

Questions submitted via Chat feature



Survey Completion for 3.25 Hours CME Credit:

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Join Our Upcoming Session:

Culture and Illness –

Implications for Clinicians and Related Health Professionals

– December 9th <https://bit.ly/3tRdeCL>

Past sessions on video: <http://www.careoregon.org/medsed>

