CURRENT BARRIERS IN TYPE 2 DIABETES DRUG THERAPY
2019

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RESOURCES

- American Diabetes Association: http://www.diabetes.org
- Centers for Disease Control & Prevention: http://www.cdc.gov/diabetes
- The DAWN (Diabetes Attitudes, Wishes, and Needs) program: http://www.dawnstudy.org
- American Diabetes Association® (ADA) 2019
- The American Association of Clinical Endocrinologists (AACE)
OVERVIEW

1. Case Studies
2. Hemoglobin A1C Goals based on ADA & AACE guidelines
3. Review of Current Recommendations Based on Guidelines
4. List of Alliance Formulary Medications
5. Factors Associated with Poor Hemoglobin A1C Control
6. Management and Resolution of the Factors Associated with Poor Hemoglobin A1C Control
7. Summary of Alliance Preferred Anti-diabetic Medications
52 YO newly diagnosed male patient with hemoglobin A1C 7.3%. Provider prescribes metformin 1000mg BID. Patient does not have any other significant comorbidities.
29 YO female patient with diabetes and A1C of 13%. Patient was diagnosed 9 years ago. She’s currently on Lantus, Humalog, metformin, alogliptin, Steglatro and Trulicity. She doesn’t test her glucose levels and states even if she does test her glucose, she doesn’t know what to do with it.
40 YO female patient with hemoglobin A1C 10%. She has had diabetes most of her life. She’s on metformin, glipizide, alogliptin, pioglitazone. The provider wants to start insulin; however, patient is afraid of needles. Provider is considering adding Steglatro instead.
Questions to consider:

- Is this an appropriate treatment regimen based on current guidelines?
- Is this a simple regimen or complicated regimen?
- Is it likely to be covered by insurance company?
- Are there any significant side effects associated with this medication?
- Have the side effects been addressed and resolved?
HEMOGLOBIN A1C GOALS FOR MOST ADULTS

<table>
<thead>
<tr>
<th>A1C</th>
<th>&lt;7.0% (53 mmol/mol)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-prandial capillary plasma glucose</td>
<td>80–130 mg/dL* (4.4–7.2 mmol/L)</td>
</tr>
<tr>
<td>Peak postprandial capillary plasma glucose†</td>
<td>&lt;180 mg/dL* (10.0 mmol/L)</td>
</tr>
</tbody>
</table>

### Approach to Individualization of Glycemic Targets

<table>
<thead>
<tr>
<th>Patient / Disease Features</th>
<th>More stringent ↔ A1C 7% ↔ Less stringent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risks potentially associated with hypoglycemia and other drug adverse effects</td>
<td>low ↔ high</td>
</tr>
<tr>
<td>Disease duration</td>
<td>newly diagnosed ↔ long-standing</td>
</tr>
<tr>
<td>Life expectancy</td>
<td>long ↔ short</td>
</tr>
<tr>
<td>Important comorbidities</td>
<td>absent ↔ few/mild ↔ severe</td>
</tr>
<tr>
<td>Established vascular complications</td>
<td>absent ↔ few/mild ↔ severe</td>
</tr>
<tr>
<td>Patient preference</td>
<td>highly motivated, excellent self-care capabilities ↔ preference for less burdensome therapy</td>
</tr>
<tr>
<td>Resources and support system</td>
<td>readily available ↔ limited</td>
</tr>
</tbody>
</table>
# Profiles of Antidiabetic Medications

<table>
<thead>
<tr>
<th></th>
<th>MET</th>
<th>GLP1-RA</th>
<th>SGLT2i</th>
<th>DPP4i</th>
<th>AGi</th>
<th>TZD (moderate dose)</th>
<th>SU GLN</th>
<th>COLSVL</th>
<th>BCR-QR</th>
<th>INSULIN</th>
<th>PRAML</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HYPO</strong></td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Moderate/Severe</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Moderate to Severe</td>
<td>Neutral</td>
</tr>
<tr>
<td><strong>WEIGHT</strong></td>
<td>Slight Loss</td>
<td>Loss</td>
<td>Loss</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Gain</td>
<td>Gain</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Gain</td>
</tr>
<tr>
<td><strong>RENAL / GU</strong></td>
<td>Contra-indicated if eGFR &lt; 30 ml/min/1.73 m²</td>
<td>Exenatide Not Indicated CrCl &lt; 30</td>
<td>Genital Mycotic Infections</td>
<td>Dose Adjustment Necessary (Except Linagliptin)</td>
<td>Effective in Reducing Albuminuria</td>
<td>Neutral</td>
<td>Neutral</td>
<td>More Hypo Risk</td>
<td>Neutral</td>
<td>Neutral</td>
<td>More Hypo Risk</td>
</tr>
<tr>
<td><strong>GI Sx</strong></td>
<td>Moderate</td>
<td>Moderate</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Moderate</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Mild</td>
<td>Moderate</td>
<td>Neutral</td>
</tr>
<tr>
<td><strong>CHF</strong></td>
<td>Neutral</td>
<td>See #1</td>
<td>See #2</td>
<td>See #3</td>
<td>Neutral</td>
<td>Moderate</td>
<td>Neutral</td>
<td>Neutral</td>
<td>CHF Risk</td>
<td>Neutral</td>
<td>Neutral</td>
</tr>
<tr>
<td><strong>ASCVD</strong></td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Moderate Fracture Risk</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
</tr>
<tr>
<td><strong>BONE</strong></td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
</tr>
<tr>
<td><strong>KETOACIDOSIS</strong></td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>DKA Can Occur in Various Stress Settings</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
</tr>
</tbody>
</table>

- **Few adverse events or possible benefits**
- **Use with caution**
- **Likelihood of adverse effects**

1. Liraglutide—FDA approved for prevention of MACE events.
2. Empagliflozin—FDA approved to reduce CV mortality. Canagliflozin—FDA approved to reduce MACE events.
3. Possible increased hospitalizations for heart failure with alogliptin and saxagliptin.
Which medications are preferred for patients with established ASCVD in addition to metformin?

A. GLP-1 agonists
B. DPP4 inhibitors
C. SGLT2 inhibitors
D. A & B
E. A & C

ASCVD: coronary heart disease, cerebrovascular disease, or peripheral arterial disease (PAD) presumed to be of atherosclerotic origin
Factors Influencing Treatment Success

Figure 1 Factors influencing treatment success (adapted from Allen et al. 2009).
DECISION CYCLE FOR PATIENT-CENTERED GLYCEMIC MANAGEMENT IN TYPE 2 DIABETES

GOALS OF CARE
- Prevent complications
- Optimize quality of life

ASSESS KEY PATIENT CHARACTERISTICS
- Current lifestyle
- Comorbidities, i.e., ASCVD, CKD, HF
- Clinical characteristics, i.e., age, HbA1c, weight
- Issues such as motivation and depression
- Cultural and socioeconomic context

CONSIDER SPECIFIC FACTORS THAT IMPACT CHOICE OF TREATMENT
- Individualized HbA1c target
- Impact on weight and hypoglycemia
- Side effect profile of medication
- Complexity of regimen, i.e., frequency, mode of administration
- Choose regimen to optimize adherence and persistence
- Access, cost, and availability of medication

REVIEW AND AGREE ON MANAGEMENT PLAN
- Review management plan
- Mutual agreement on changes
- Ensure agreed modification of therapy is implemented in a timely fashion to avoid clinical inertia
- Decision cycle undertaken regularly (at least once/twice a year)

ONGOING MONITORING AND SUPPORT INCLUDING:
- Emotional well-being
- Check tolerability of medication
- Monitor glyemic status
- Biofeedback including SMBG, weight, step count, HbA1c, blood pressure, lipids

IMPLEMENT MANAGEMENT PLAN
- Patients not meeting goals generally should be seen at least every 3 months as long as progress is being made; more frequent contact initially is often desirable for DSMES

AGREE ON MANAGEMENT PLAN
- Specify SMART goals:
  - Specific
  - Measurable
  - Achievable
  - Realistic
  - Time limited

SHARED DECISION MAKING TO CREATE A MANAGEMENT PLAN
- Involves an educated and informed patient (and their family/caregiver)
- Seeks patient preferences
- Effective consultation includes motivational interviewing, goal setting, and shared decision making
- Empowers the patient
- Ensures access to DSMES

ASCVD = Atherosclerotic Cardiovascular Disease
CKD = Chronic Kidney Disease
HF = Heart Failure
DSMES = Diabetes Self-Management Education and Support
SMBG = Self-Monitored Blood Glucose
<table>
<thead>
<tr>
<th>Patient Specific Barriers</th>
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</thead>
<tbody>
<tr>
<td>Poor Health Literacy</td>
</tr>
<tr>
<td>Denial or Absence of Symptoms</td>
</tr>
<tr>
<td>Complex Regimen</td>
</tr>
<tr>
<td>Inconvenience</td>
</tr>
<tr>
<td>Side Effects</td>
</tr>
<tr>
<td>Fear</td>
</tr>
<tr>
<td>Cost</td>
</tr>
<tr>
<td>Mental Illness</td>
</tr>
<tr>
<td>Lifestyle</td>
</tr>
<tr>
<td>Feeling of Failure</td>
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</tbody>
</table>

**RESOLUTION:**
- Diabetes Education (DSME or DSMT) by a Multidisciplinary Team
- Patient Self Empowerment/Self Management Skills
- Patient Involvement in Decision-Making.
- Simplifying Regimen
- Addressing Side Effects
- Addressing Overall Health
<table>
<thead>
<tr>
<th>Clinician Specific Barriers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insufficient Time</td>
</tr>
<tr>
<td>Lack of Clinical Resources</td>
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<tr>
<td>Staff Shortages</td>
</tr>
<tr>
<td>Failure to Initiate or Set Clear Treatment Goals</td>
</tr>
<tr>
<td>Reactive vs Proactive</td>
</tr>
<tr>
<td>Authoritative Treatment Strategy</td>
</tr>
</tbody>
</table>

**RESOLUTION:**
- Involve Multidisciplinary Team
- Seminars And CEs
- Set Clear And Practical Goals
- Be Honest With Patients
- Avoid Clinical Inertia
- Involve Patient in Decision-Making
<table>
<thead>
<tr>
<th>Health Care Barriers</th>
<th>RESOLUTION:</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Decision Support</td>
<td>• Multidisciplinary Team involving Doctors, Nurses, Pharmacists, Dietician, Educations and Social Workers.</td>
</tr>
<tr>
<td>No Active Patient Outreach</td>
<td></td>
</tr>
<tr>
<td>No Team Approach / Lack of Coordination</td>
<td></td>
</tr>
<tr>
<td>No Disease Registry</td>
<td></td>
</tr>
<tr>
<td>Lack of Follow-Up</td>
<td></td>
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<tr>
<td>Insurance Issues</td>
<td></td>
</tr>
<tr>
<td>Barriers that Overlap</td>
<td>Poor Communication</td>
</tr>
<tr>
<td>----------------------</td>
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</tbody>
</table>

**RESOLUTION:**
- Utilize Alliance Cultural and Linguistic Services
<table>
<thead>
<tr>
<th>Barriers Specific to Alliance Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access to Providers and Pharmacies</td>
</tr>
<tr>
<td>Homelessness</td>
</tr>
<tr>
<td>Fears (Illegal Status, Failure)</td>
</tr>
<tr>
<td>Non-Adherence</td>
</tr>
<tr>
<td>Lifestyle</td>
</tr>
<tr>
<td>Complex Regimen</td>
</tr>
<tr>
<td>Lack of Trust</td>
</tr>
<tr>
<td>Complex Insurance Problems</td>
</tr>
<tr>
<td>Lack of Education</td>
</tr>
<tr>
<td>Mental Health Issues</td>
</tr>
</tbody>
</table>

**RESOLUTION:**
- Involve CCAH Care Management Team
- Utilize CCAH Transportation Program
- Utilize Alliance Cultural and Linguistic Services
Factors that can influence treatment success may include the following:

A. Patients
B. Clinicians
C. Health Care System
D. All of the above
52 YO newly diagnosed male patient with hemoglobin A1C 7.3%. Provider prescribes metformin 1000mg BID. Patient does not have any other significant comorbidities.

- Yes, it is based on current guidelines
- It is a simple regimen
- Metformin ER is available as Glucophage XR (as 500mg only), Fortamet & Glumetza
- Yes, metformin is associated with gastrointestinal side effects such as diarrhea, nausea, and vomiting. To help with these side effects, it’s better to start at a low dose like generic Glucophage XR 500mg daily, titrate gradually to twice daily and eventually to 2 tablets BID. Also, remember to recommend to take medication with meals.
29 YO female patient with diabetes and A1C of 13%. Patient was diagnosed 9 years ago. She’s currently on Lantus, Humalog, metformin, alogliptin, Steglatro and Trulicity. She doesn’t test her glucose levels and states even if she does test her glucose, she doesn’t know what to do with it.

- Refer to a specialist
- Complicated regimen
- Brand names like Lantus, Humalog, Steglatro and Trulicity will likely require PA
40 YO female patient with hemoglobin A1C 10%. She has had diabetes most of her life. She’s on metformin, glipizide, alogliptin, pioglitazone. The provider wants to start insulin; however, member is afraid of needles. Provider is considering adding Steglatro instead.

- Clinical Inertia?
- According to AACE guidelines, patients taking two oral anti-hyper-glycemic agents who have an A1C >8.0% and/or long-standing T2D are less likely to reach their target A1C with a third oral antihyperglycemic agent.
- Start with a GLP-1 agonist that in most cases can be injected on weekly basis and then slowly transition over to basal insulin.
Alliance Care Management (CM) works with individuals to improve their health and quality of life.

These services are voluntary and available to all eligible members. Alliance Services include:

- Healthy Weight for Life
- Wellness that Works Support Program (formerly known as Weight Watchers)
- Live Better with Diabetes
- Tobacco Cessation Program
- Complex Case Management

Alliance Care Management Services Referrals and Contact: (800) 700-3874 ext. 5512 or www.ccah-alliance.org/case_management.html

Alliance Cultural and Linguistic Services: (800) 700-3874 ext. 5580 or www.ccah-alliance.org/cultural_linguistic.html

Alliance Transportation Referrals, please contact Member Services: (800) 700-3874 ext. 5577
Members can self-refer to the Alliance Care Management program and/or contact Transportation services if need be?

A. True
B. False
The Alliance provider webpage has valuable resources:

- Pharmacy **Formulary**
- Quick Reference Guides: **Diabetes**
- Prior Authorization **Form**
- Prior Authorization **Criteria**

http://www.ccah-alliance.org/pharmacy.html
Go to: http://www.ccah-alliance.org/
DIABETES REFERENCE GUIDE

Go to: http://www.ccah-alliance.org/

***Quick reference guide for formulary testing supplies, preferred medications & PA criteria for common diabetic medications.
Alliance Preferred Antidiabetic Medications Summary

- **Biguanide**
  - Metformin (Glucophage)
  - Metformin ER (Glucophage XR)

- **SU**
  - Glipizide
  - Glimepiride
  - Glyburide

- **AGi**
  - Acarbose

- **TZD**
  - Pioglitazone

- **GLP-1 Agonist**
  - Trulicity*
  - *Requires Prior Authorization

- **SGLT-2 Inhibitor**
  - Steglatro

- **DPP-4 Inhibitor**
  - Alogliptin

- **Fast Acting Insulin**
  - Admelog Pen and Vial

- **Long Acting Insulin**
  - Basaglar Pen and Vial

* Requires Prior Authorization
PRIOR AUTHORIZATION CRITERIA (PDF)

Go to: http://www.ccah-alliance.org/

Prior Authorization Criteria:
The Alliance’s Prior Authorization Criteria outlines the general criteria by which non-formulary drugs can be prescribed. Exceptions to these criteria are made on a case-by-case basis through the prior authorization process. The Alliance prior authorization criteria is developed by our P&T Committee and is reviewed at least annually.

Click here to view our Prior Authorization Criteria (PDF).
SUBMITTING PRIOR AUTHORIZATIONS

1. Provider Portal (e-portal)
2. Fill out Prior Authorization form & submit via fax

Both options can be initiated via Alliance website:

http://www.ccah-alliance.org/
E-PORTAL PA SUBMISSION

Go to: http://www.ccah-alliance.org/

Providers Home Page
Provider Portal
Claims
Provider Manual
Pharmacy Services

The Alliance’s Provider Portal offers quick and easy online access to the tools and information you need to streamline your administrative processes.

Click on the button at the left to log in.

Alliance Provider Services: (800) 700-3874 ext. 5504
FAXED PA SUBMISSION

- Go to: http://www.ccah-alliance.org/

Prior Authorizations
To submit a prior authorization:

1. Fax. [Click here](http://www.ccah-alliance.org/) for the Prior Authorization (PA) form.

Alliance Pharmacy Department Fax: 831-430-5851
TIPS FOR A QUICK APPROVAL

• Submit prior authorization completed to best ability
• Submit any supporting documentation/ recent chart notes along with PA request
• Document any reactions, side effects, allergies, intolerance to related medications (i.e Metformin)
• If a medication is required immediately in emergency situations, dispensing pharmacies may call MedImpact at (800) 788-2949 to obtain an override up to 5 day supply while the request is under review.


- Breaking Down Patient and Physician Barriers to Optimize Glycemic Control in Type 2 Diabetes. The American Journal of Medicine (2013) 126, S38-S48

- Strategies for Improving Care. Diabetes Care 2016;39(Suppl. 1):S6–S12

QUESTIONS?

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Alliance Provider Services: (800) 700-3874 ext. 5504

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