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**DEPARTMENT OF
HEALTH AND HUMAN SERVICES**
DIVISION OF HEALTH CARE FINANCING AND POLICY
Helping people. It's who we are and what we do.



Stacie Weeks,
JD MPH
Administrator

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**Notice of Meeting to Solicit Public Comments and Intent to Act Upon Amendments to the
Medicaid Services Manual (MSM)**

**Public Hearing January 30, 2024
Summary**

Date and Time of Meeting: January 30, 2024, at 10:12 AM

Name of Organization: State of Nevada, Department of Health and Human Services (DHHS), Division of Health Care Financing and Policy (DHCFP)

Place of Meeting: DHCFP
1100 E. William Street
Second Floor Conference Room
Carson City, Nevada 89701

Teleconference and/or Microsoft Teams Attendees

(Note: This List May Not Include All Participants, Just Those Who Identified Themselves)

Malinda Southard, Deputy Administrator, DHCFP
Gabriel Lither, Senior Deputy Attorney General
Casey Angres, DHCFP
Jessica Vannucci, DHCFP
Carin Fox Hennessey, DHCFP
Lisa Dyer, DHCFP

Stephanie Sadabseng, DHCFP
Amber Cronn, DHCFP
Gladys Cook, DHCFP
Thomas Fletcher, DHCFP
April Caughron, DHCFP
Dominic Gaon, Anthem
Melody Hall-Ramirez, DHCFP
Sarah Dearborn, DHCFP
Keith Benson, DHCFP
De
Linda Anderson, Nevada Public Health Foundation
(NPHF)
Marcel Brown, DHCFP

Keiko Duncan, DHCFP
Michelle Soule,

Sean Linehan, DHCFP
Patrick Kelly, Nevada Hospital Association (NVHA)
Betti Magney, Vitality Unlimited
Elizabeth Scott, DHCFP
Michelle Guerra, Nevada Behavioral Health Systems
(NVBHS)
Mandy Coscart, DHCFP
Rafat Fields, Abbot
Patrick J. Crabb, Silver Summit Health Plan (SSHP)
Christy Nguyen, Fidelis-RX
Sandra Stone, Division of Child and Family Services
(DCFS)
Belz & Case Government Affairs-Scribe by Rewatch
Rianna White, Fidelis-Rx
Tashanae Glass, DHCFP
Allison Genco, Dignity Health
Erin Lynch, NVHA

Tianna Pena, FirstMed Health and Wellness (FMHWC)
Kristen Davis-Coelho, Northern Nevada HOPES
(NNHOPES)
Amy Carl, Anthem
Amy Chattin, DHCFP
Brooke Gruger, Liberty Dental Plan (LIB)
Lilnetra Grady, FMHWC
Candace McClain-Williams, DHCFP
Elena Litton, NNHOPES
Kimberly Adams, DHCFP
Steve Messinger, Nevada Primary Care Association
(NVPCA)
Kimberly Lambrecht, NVPCA
Keri Kelley, SSHP
Michael McCabe, Sellers Dorsey
Hannah Branch, Ferrari Reeder Public Affairs (FRPA)
Philip Ramirez, Molina Healthcare
Morgan Biaselli, SSGR
Chrissy Sanders, SSHP
Dorothy A. Edwards, Washoe County
Saundra Heller, CareSource
Dena Brennan, Gainwell Technologies (GWT)
Jessica Mandoki, DHCFP
Sandie Ruybalid, DHCFP
Serene Pack, DHCFP
Sheri Gaunt, DHCFP
Ellen Flowers, DHCFP
Alex Tanchek, Silver State Government Relations
Theresa Carsten, DHCFP
Amy Levin, MD, Anthem
Mary Gilbertson, UCare
Sarah Rubino Caldwell, Sellers Dorsey
Brandon Ford, Silver State Health
Sabrina Schnur, Belz & Case

William B. Wilhelmsen, Abbott Diabetes Care
Christine Fallabel, American Diabetes Association
Dawnesha Powell, SSHP
Steve
Mariham Fahim, Abbott Diabetes Care
David Nunez, Medcor, Inc.
Maria Reyes, Fidelis-Rx
Robin Ochsenschlager, DHCFP
Nicole L. Figles, SSHP
Ferrari Reeder
Lucille Wroldsen, DHCFP
Brian Evans, The Perkins Company
Carissa Pearce, Children's Advocacy Alliance of Nevada
Holly Long, Community Health Alliance (CHA)
Nik Rose, FMHWC
Suzanne Bierman, Sellers Dorsey
Lovia Larkin, Vitality Unlimited
Hilal Arshad, Elevance Health
Rachelle R
Jason Douglas, Novo Nordisk
Laurie Curfman, LIB
M. Wilson
Mari Nakashima Nielsen, The Perkins Company
Brooke Greenlee, Elevance Health
Vimal Asokan, Anthem
Robert Spadaccini, Sellers Dorsey
Denise Hanlin,
(SAFY)
Jenny Contreras, Medcor, Inc.
Celina
Ky Plaskon, DHCFP
Cara Paoli, Washoe County
Regina C. De Rosa, Anthem

Introduction:

Casey Angres, Chief of Division Compliance, DHCFP, opened the Public Hearing introducing herself, Malinda Southard, Deputy Administrator, DHCFP, and Gabriel Lither, Senior Deputy Attorney General.

Casey Angres – The notice for this public hearing was published on December 28, 2023, in accordance with Nevada Statute 422.2369.

- 1. Public Comments:** Mariham Fahim advised she is giving testimony regarding Continuous Glucose Monitoring (CGM). She thanked the committee for the recent workshop in the effort of providing more to these eligible patients with Type II Diabetes with increased coverage for CGM. It is known that diabetes is becoming an epidemic and Type II Diabetes accounts for about 95% of this epidemic. Recent economic data estimates \$412 billion in medical expenses managing Type II Diabetes. Providing and prioritizing these patients is necessary to get optimal glycemic control and can save the state billions of dollars. The

value of the CGM metrics in helping these people with diabetes achieve their glycemic goals, and doing so safely, is recognized by the national organizations that have shifted some of their standards to include the CGM metrics. Recently the National Committee for Quality Assurance (NCQA) added the CGM metric glucose management indicator as a reporting quality metric as an alternative to HbA1c for their heat as 2024 measures. Other standard setting organizations such as American Association of Clinical Endocrinology (AACE) recommend CGM for all insulin using patients and those at risk of hypoglycemia to reach their glycemic goals safely. They also state that internally scanned CGM could be a helpful tool for newly diagnosed Type 2 Diabetes patients and those at risk of hypoglycemia. The American Diabetes Association (ADA) states the clinicians should exercise judgment when using A1C alone as the sole basis for assessing glycemic control. They recommend the inclusion of CGM metrics such as glucose variability and time and range. The current Centers for Medicare and Medicaid Services (CMS) coverage policy extends this eligibility to beneficiaries who are using insulin at least one administration per day and have at least one documented hypoglycemic event. Mariham Fahim advised they respectfully ask that Nevada Medicaid aligns to these current standards of care and the CMS guidelines by removing the full-finger stick-a-day requirement as it has no supporting data, and this requirement was removed from CMS in July 2021. She advised they also request the expansion of the policy to cover all insulin using patients. Clinical studies suggest that a statistically significant 1.1% reduction in A1C and persons with Type 2 Diabetes are treated with basal insulin only. The economic studies suggest that lowering the A1C by even 1% is associated with a \$429 reduction in cost. This also translates into improved outcomes in terms of hospitalization, acute diabetes events (up to 67% fewer Diabetic ketoacidosis (DKA) admissions), and 75% and 44% fewer admissions for severe hypoglycemia. These results are sustained in the study for over two years. Diabetes care really supports Nevada Medicaid and their intention to expand the coverage for CGM for Type 2 Diabetes patients. She pointed out that the current policy is still not in alignment with CMS or the current standard of care that recommends CGM for all insulin using patients and those at risk of hypoglycemia. She advised they wanted to give a big thanks for the Division's intention to cover this and to ask the Division to continue to prioritize these patients as this could be very cost saving for the state through avoidable facility organizations.

2. Discussion and Proposed Adoption and Changes to MSM 1200

Subject: MSM Chapter 1200 – Prescribed Drugs

Jessica Vannucci, Social Service Program Specialist Supervisor, DHCFP, Pharmacy and Durable Medical Equipment (DME) Unit, presented revisions to MSM Chapter 1200 are being proposed to update the links within Appendix B to prior authorization forms and preferred drug list and to add coverage for continuous glucose monitors (CGM) for recipients with Diabetes Mellitus II (Type II) to align with standards of care.

The expected impact on local government is a fiscal savings to DHCFP.

Public Comments: There were none.

Malinda Southard approved the changes, pending spelling and grammar checks.

Casey Angres – Closed the Public Hearing for proposed adoption and changes to MSM Chapter 1200 – Prescribed Drugs.

3. Discussion and Proposed Adoption and Changes to MSM 1200

Subject: MSM Chapter 1200 – Prescribed Drugs

Dr. Keiko Duncan, Pharmacy Director for Pharmacy Services, DHCFP, presented the proposed revisions to MSM 1200 – Prescribed Drugs, based on recommendations approved at the October 19, 2023, Drug Utilization Review (DUR) Board Meeting.

The proposed changes include: Addition of Spevigo® (spesolimab-sbzo) under therapeutic class “Immunomodulator Drugs.” Addition of Elevidys™ (Delandistrogene Moxeparovec-Rokl) under therapeutic class “Duchenne Muscular Dystrophy (DMD) Agents.” Addition of Qalsody™ (Tofersen) under therapeutic class “Amyotrophic Lateral Sclerosis (ALS).” Created a new section for Vyjuvek™ (beremagene geperpavec-svdt) for therapeutic class “Dystrophic epidermolysis bullosa (DEB).” Created a new section for Hemgenix® (etranacogene dezaparovec-drlb) for therapeutic class Hemophilia B. Created a new section for Roctavian™ (valoctocogene roxaparovec-rvox) for therapeutic class “Hemophilia A.” Created a new section for Evkeeza™ (evinacumab-dgnb) for therapeutic class “Antihyperlipidemic – angiopoietin-like protein 3 (ANGPTL3).” Created a new section for Joenja® (Leniolisib) for therapeutic class “activated phosphoinositide 3-kinase delta (PI3K

Updated prior authorization link throughout the document. Updated the “Last Reviewed by DUR Board” date.

There is no financial impact on local government known.

The effective date of these changes is February 5, 2024.

Public Comments: There were none.

Malinda Southard approved the changes, pending spelling and grammar checks.

Casey Angres – Closed the Public Hearing for proposed adoption and changes to MSM Chapter 1200 – Prescribed Drugs.

4. Discussion and Proposed Adoption and Changes to MSM 400

Subject: MSM Chapter 400 – Mental Health and Alcohol/Substance Use Services

Marcel Brown, Program Specialist, Behavioral Health Benefits Coverage Unit, DHCFP, presented revisions to Nevada MSM Chapter 400 - Mental Health and Alcohol and Substance Use Services are being proposed to update Section 403.6 (I) Mobile Crisis Response Delivered by Designated Mobile Crisis Teams. Section 403.6I(1) - Mobile Crisis Response Delivered by Designated Mobile Crisis Team (DMCT), Scope of Services, clarification has been made to identify the location of the response to the family’s location of choice. This section has been updated to clarify that children 18 years or younger and adults in urban Clark and Washoe Counties responses will be conducted with an average response time within one hour. For children 18 years or younger and adults in rural counties, responses will be within two hours. Telehealth responses for all ages shall occur as soon as possible but no longer than one hour. In-person responses to telehealth calls shall arrive within one hour in urban areas and within two hours in rural areas.

Section 403.6I(3)(b)(7), DMCT Operational Requirements, Peer-to-Peer Support Services: Clarification has been made to add one member of the DMCT team should be a “Certified” Peer and Recovery Support Services Provider as required by the “Nevada Certification Board.”

Section 403.6I(4)(d)(8), DMCT Provider Eligibility Requirements: Clarification has been made to identify Peer Supporters operating as DMCT members should be “Certified” as a Peer Supporter as required by the “Nevada Certification Board.”

These proposed changes affect all Medicaid-enrolled providers delivering Outpatient Behavioral Health Services. Those PTs include but are not limited to Certified Community Behavioral Health Center (PT 17, Specialty 188)- and Crisis Services (PT 87).

No financial impact is currently anticipated for local government as a result of these changes.

The effective date of this proposed policy is January 31, 2024.

Public Comments: There were none.

Malinda Southard approved the changes, pending spelling and grammar checks.

Casey Angres – Closed the Public Hearing for proposed adoption and changes to MSM Chapter 400 – Mental Health and Alcohol/Substance Use Services.

5. Discussion and Proposed Adoption and Changes to MSM Chapter 2900 - Federal Qualified Health Centers

Subject: MSM Chapter 2900 – Federal Qualified Health Centers

Carin Fox Hennessey, Medical Benefits Coverage Unit Program Specialist, DHC FP, presented the updates to MSM Chapter 2900, Federally Qualified Health Centers, related to Mental/Behavioral Health encounters. Revisions to MSM Chapter 2900 are being proposed to clarify language around Mental/Behavioral Health encounters. The updated language identifies qualified providers of Mental/Behavioral Health encounter Services. Providers shall deliver services under the scope and practice of their licensure using appropriate diagnostic tools for behavioral health treatment. Language around mental health and substance use treatment including co-occurring treatment has been updated in alignment with MSM Chapter 400.

Entities Financially Affected: The proposed updates affect all Medicaid-enrolled providers delivering mental health and substance use treatment including co-occurring treatment services in a Federally Qualified Health Center setting. Those PTs include but are not limited to: Behavioral Health, Outpatient Treatment (PT 14), Psychologist (PT 26), Special Clinics (PT 17, Specialty 181).

Financial impact on local government: Unknown at this time.

Effective date: January 31, 2024.

The changes are as follows: Section 2901.A: Addition of the Public Health Services Act to the authorities, for clarification. Section 2903.D(1): Clarification of Licensed Psychologists and Licensed Marriage and

Family Therapists (LMFT), as qualified providers of FQHC encounters. Section 2903.1(B): Consistent use of the term “Mental/Behavioral Health” encounter has been applied to this chapter. Section 2903.1(B)(1): Clarification of the independently licensed behavioral health providers able to bill Mental/Behavioral Health encounters. Section 2903.1(B)(2): Clarification of enrollment of QMHPs and delivery of services under a Behavioral Health Community Network (BHCN) model. Clarification of Mental/Behavioral Health encounter service providers to include LCSW and LMFT interns under appropriate supervision under the FQHC delivery model. Clarification that services delivered by Licensed Clinical Professional Counselors (LCPC), LCPC interns, or psychological interns, assistants, and trainees are not reimbursable under the Mental/Behavioral Health encounter. Section 2903.1(B)(3): Clarification of covered conditions and allowable services under the Mental/Behavioral Health encounters, including substance use and co-occurring disorders delivered by an appropriately licensed provider. Section 2903.1(B)(4): Clarification of documentation requirements of all Mental/Behavioral Health encounters. Section 2903.2(A)(1): Clarification of non-billable group therapy services under Mental/Behavioral Health encounters. Section 2903.2(A)(2): Clarification of non-billable services included as part of the FQHC encounter. Sections 2903.6 and 2903.7: Additional language to include federal and state regulations.

Public Comments: Brandon Ford commented that he shared the link for CMS.gov which is effective January 1, 2024. The Clinical Professional Counselors (CPC) were recognized and he feels the policies are being adjusted after the fact and he would like to see if DHCFP could hold off on making any changes to the chapter until this can be reviewed to make sure it is in line with the new federal guidelines.

Carin Fox Hennessey replied that currently under the DHCFP budget, CPC or the CPC interns are not included. However, the Division is committed to reviewing MSM Chapter 2900 to improve and expand the policy during the next Legislative Session, and anything needing to be done sooner. Currently it is not included in the updates of the chapter for Mental/Behavioral Health encounters.

Brandon Ford asked if there is a way to hold off making the updates as the changes were just made effective January 1, 2024. He continued by adding he thought DHCFP is splitting the board and it kind of creates a division among the MFT and the CPCs, which probably is not going to be received well. It is kind of like dividing them. They go through the same educational requirements and must follow the same board guidelines. He again asked if there is any way DHCFP could just delay until the Legislative Session and then make those changes.

Theresa Carsten, Deputy Administrator for Medical Benefit Coverage, replied she thinks DHCFP is going to move forward with this change. She advised Brandon Ford to send the information he is describing to her through the hearing. Theresa Carsten said she thinks if there is a CMS mandate to cover something, then DHCFP will try to find a way to move it forward. If it is an optional coverage kind of thing, then it is something that must be taken to Legislative Session to get budget authority and legislative approval to cover it. She reiterated DHCFP will need to move forward with this as it impacts current FQHC processes that have been talked to with specifically one FQHC. DHCFP does not wish to lose this coverage. Theresa Carsten added she would be happy to review the documents Brandon Ford sends.

Brandon Ford thanked Theresa Carsten.

Carissa Pearce advised she works with The Children's Advocacy Alliance. The Children's Advocacy Alliance is a nonpartisan, independent, nonprofit organization that aims to cultivate public policy that allows every child in Nevada to thrive. As such, they are strongly in support of any actions that increase access to and delivery of mental and behavioral health resources along the continuum, including during mental health crises and the follow-up care. It is imperative to address the mental health disparities facing children and families in the state. The pandemic exacerbated existing challenges that are faced in mental health service

delivery in Nevada. Children and adolescents are at an increased risk for poor mental health outcomes resulting from the lack of access to a continuum of mental health supports in Nevada. According to the Nevada Youth Risk Behavior Survey, between 2019 and 2021 there was a significant increase in the number of high school students who consistently felt sad or hopeless. Who seriously considered attempting suicide. Who made a plan for attempting suicide. Who did attempt suicide and those who purposely hurt themselves. It is noteworthy that the study also showed an increase in those who felt they never, or rarely, received the help they needed. Our kids know that we don't have the systems to support them, and they are suffering for it. The Children's Advocacy Alliance has recently formed a child mental health action coalition to gather folks across the field to form a cohesive policy agenda to address the children's mental health. They also support the work of the coalition stretch as Hope Means Nevada and the Mobile Crisis Response Team as leaders in this space. The proposed changes discussed today in items four and five clarify elements of the delivery of care for the Mobile Crisis Team and clinical care. These changes are just the beginning of the efforts needed to properly provide mental and behavioral support. State programs are needed that provide mental health resources along the full continuum of care. This will allow children to stay with their families and loved ones and not be sent out-of-state where they are the most vulnerable. This also means families would not have to rely on emergency care and the foster care system to meet their child's mental health needs. Carissa Pearce advised they are very grateful for this conversation and to please continue this work around mental and behavioral health services in Nevada so we can save the lives of our youth.

Kristen Davis-Coelho asked for clarification to make sure she got the correct provider types with the update. She asked if the "Yeses" now include the Licensed Clinical Social Workers (LCSW), Licensed Marriage and Family Therapists (LMFT's), as well as LCSW interns, and MFT interns; and the "No's" at this point are CPC's, CPC interns, and she said she believed it was listed the psychological trainees assistants and interns. She asked if that was correct for the psychologist track.

Carin Fox Hennessey advised that was correct.

Kristen Davis-Coelho replied okay, and asked if that includes both pre-doctoral psychology trainees and post-doctoral psychology interns.

Carin Fox Hennessey replied the psychological interns, assistants, and trainees operate under the clinical psychologist. She advised she could research this more, but she believed that would be a separate enrollment, not under the FQHC. If the interns, assistants, and trainees were going to be operating under that clinical psychologist license, it would be under a separate, likely Psychologist (PT 26), enrollment working with the FQHC.

Kristen Davis-Coelho said okay, so they are not excluded as they would just need to go under the Psychologist (PT 26) provider.

Carin Fox Hennessey replied that is correct.

Steve Messinger, Nevada Primary Care Association, commended the Division for responding to real concerns that were raised the first time this proposal came around. He said they are grateful the Division was able to understand it was causing a disruption and to change course.

Malinda Southard approved the changes, pending spelling and grammar checks.

Casey Angres – Closed the Public Hearing for MSM Chapter 2900 – Federal Qualified Health Centers.

6. Adjournment

There were no further comments and Casey Angres closed the Public Hearing at 10:36 AM.

****An Audio (CD) version of this meeting is available through the DHCFP Compliance office. For more detailed information on any of the handouts, submittals, testimony and or comments please contact Jenifer Graham at documentcontrol@dhefp.nv.gov with any questions.***

Executive Testimony for Nevada Medicaid

Thank you for allowing me to present today. My name is Mariham Fahim, I am a contingent Medical Outcomes Manger for Abbott Diabetes Care

It has been well established that optimal glucose control is critical to effective diabetes management to prevent and delay micro and macro vascular disease.^{1,2} Traditionally there have been two glycemic assessment tools, glycated hemoglobin (HbA1c) and self-monitoring blood glucose (SMBG), but both tools have significant limitations.^{3,4} HbA1c provides only a glucose average and lacks the ability to identify glycemic excursions and acute hypoglycemic events.³ SMBG only provides a glucose measurement at that moment in time and does not provide hypo and hyperglycemic trending. In addition, SMBG is often associated with pain and inconvenience where the data reveals that only 1 out of 3 patients adhere to provider recommendations.⁴ In addition, only 50% of people with diabetes are achieving the recommended glucose target goals despite recent advances in therapeutic options.⁵

Continuous glucose monitoring (CGM) continuously measures interstitial glucose and provides comprehensive, patient- centered actionable data and is becoming Standard of Care in insulin using patients.^{6,7}

Depending on the device, CGM indications and features may include^{8,9,10}:

- Use for age 2 and older, as well as pregnancy
- Real-time glucose data plus trend arrows that illustrate the direction glucose is trending in real-time
- Historical graphs that illustrate glucose variability and patterns
- Customizable alarms* that alert the user when their glucose level goes out of range⁷
- Ability to share data^{††} with providers and caregivers
- Reports that illustrate glycemic metrics that include Time in Range and Glucose Management Indicator which the ADA recommends as an alternative to HbA1c.
- Integration with Automated Insulin Delivery Systems¹⁰

ADA and AACE endorse use of CGM in people living with diabetes treated with insulin.^{6,7} On April 16, 2023, CMS revised coverage policy for CGM (L33822) went into effect. This extends CGM eligibility to beneficiaries with diabetes who use insulin (at least 1 administration/day) including those on basal-only therapy, plus those documented as having at least one problematic hypoglycemia event.^{9,11¶}

Executive Testimony

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The latest clinical evidence include:

- A Randomized Controlled Trial (RCT) of Type 1 Diabetes (T1D) on intensive insulin therapy demonstrated a, 0.5% A1c reduction compared to BGM (blood glucose monitoring), a daily 2 hour increase in time in range (70-180mg/dl), a 43-minute decrease in time below range (<70mg/dl) and an 86-minute decrease in time above range (>180mg/dl).¹²

The FreeStyle Libre 3 system is indicated for use in people with diabetes age 4 and older.

For the FreeStyle Libre 3 system:

* Notifications will only be received when alarms are turned on and the sensor is within 33 feet unobstructed of the reading device. You must enable the appropriate settings on your smartphone to receive alarms and alerts, see the FreeStyle Libre 3 User's Manual for more information.

› Default range is 70-180 mg/dL. Consult with a healthcare professional on individual target glucose range.

^ The LibreView data management software is intended for use by both patients and healthcare professionals to assist people with diabetes and their healthcare professionals in the review, analysis and evaluation of historical glucose meter data to support effective diabetes management. The LibreView software is not intended to provide treatment decisions or to be used as a substitute for professional healthcare advice.

† The LibreLinkUp app is only compatible with certain mobile device and operating systems. Please check www.librelinkup.com for more information about device compatibility before using the app. Use of the LibreLinkUp app requires registration with LibreView. LibreLinkUp is not intended to be used for dosing decisions. The user should follow instructions on the continuous glucose monitoring system. LibreLinkUp is not intended to replace self-monitoring practices as advised by a physician.

‡ The user's device must have internet connectivity for glucose data to automatically upload to LibreView and to transfer to connected LibreLinkUp app users.

- A retrospective study examined 3,036 Medicaid adults with Type 2 Diabetes (T2D) and showed CGM use was associated with a statistically significant HbA1c reduction of 1.2%. This outcome was comparable between major racial/ethnic groups and those with higher fill adherence achieved greater HbA1c reduction (1.4% vs 1.0%). The study mentioned that elimination of CGM cost barriers can reduce racial/ethnic disparities in CGM uptake and reduce HbA1c in adults with T2D.¹³
- A RCT demonstrated an A1c reduction of 0.82% versus 0.3% for blood glucose monitoring in intensively treated people with T2D.¹⁴
- A meta-analysis showed sustained reductions in A1C of 0.45% over 12 months in people with T2D.¹⁵
- A real-world evidence study showed an A1C reduction of 1.4% in an analysis of T2D patients on basal insulin.¹⁶
- Lowering A1c by 1% is associated with a \$429 reduction in costs.¹⁷
- An observational study showed a 61% reduction in acute diabetes events and a 32% reduction in hospitalizations in intensively treated T2D patients following CGM acquisition¹²; those on basal insulin saw a 37% reduction in acute diabetes events.¹⁸
- In comparative real-world analysis of US-only matched patient groups, the FreeStyle Libre Portfolio systems was shown to achieve similar reductions in A1c and had similar rates for acute diabetes events and hospitalizations compared to a competitor CGM system.¹⁹

Health equity is a major contributor to poor diabetes outcomes.²⁰ The ADA Health Equity bill of rights advocates access to medical technologies like CGM for people living with diabetes in the lowest income brackets to help improve outcomes and close the gap on inequalities.²¹

Executive Testimony

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Lastly, CMS recently eliminated the 4 tests/day BGM requirement citing lack of evidence supporting the criteria.^{11¶}

[* Data from this study was collected with the outside US version of the FreeStyle Libre 14 day system. FreeStyle Libre 3 has the same features as FreeStyle Libre 14 day system with real-time glucose alarms. Therefore the study data is applicable to both products.

^ Data from this study was collected with the outside US version of the FreeStyle Libre 14 day system. FreeStyle Libre 2 has the same features as FreeStyle Libre 14 day system with real-time glucose alarms. Therefore the study data is applicable to both products.

¶ Abbott provides this information as a courtesy, it is subject to change and interpretation. The customer is ultimately responsible for determining the appropriate codes, coverage, and payment policies for individual patients. Abbott does not guarantee third party coverage or payment for our products or reimburse customers for claims that are denied by third party payors.]

We Respectfully Ask:

- CGM coverage be expanded to the T2D patient administering insulin.
- SMBG requirement (4 test-strips/day) to be eliminated in alignment with CMS's CGM criteria^{11¶}.

¶ Abbott provides this information as a courtesy, it is subject to change and interpretation. The customer is ultimately responsible for determining the appropriate codes, coverage, and payment policies for individual patients. Abbott does not guarantee third party coverage or payment for our products or reimburse customers for claims that are denied by third party payors.

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Important Safety Information

FreeStyle Libre 2 and FreeStyle Libre 3 systems: Failure to use FreeStyle Libre 2 or FreeStyle Libre 3 systems as instructed in labeling may result in missing a severe low or high glucose event and/or making a treatment decision, resulting in injury. If glucose alarms and readings do not match symptoms or expectations, use a fingerstick value from a blood glucose meter for treatment decisions. Seek medical attention when appropriate or contact Abbott at 855-632-8658 or <https://www.FreeStyle.abbott/us-en/safety-information.html> for safety info.

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