The New England Comparative Effectiveness Public Advisory Council

An Action Guide for Type 2 Diabetes Management

Next Steps for Payers: New England

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Completed by:

The Institute for Clinical and Economic Review

ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

Introduction

About ICER and CEPAC

The Institute for Clinical and Economic Review (ICER) is an independent non-profit health care research organization dedicated to improving the interpretation and application of evidence in the health care system. The New England Comparative Effectiveness Advisory Council (CEPAC) is one of ICER's two core programs. CEPAC is a regional body whose goal is to provide objective, independent guidance on the application of medical evidence to clinical practice and payer policy decisions across New England. Backed from a consortium of New England state health policy leaders, CEPAC holds public meetings to consider evidence reviews of a range of topics, including clinical interventions and models for care delivery, and provides judgments regarding how the evidence can best be used across New England to improve the quality and value of health care services. ICER manages the day-to-day operations of CEPAC as one of its core programs designed to translate and implement evidence reviews to improve their usefulness for patients, clinicians, payers, and policymakers.

About this Guide

This document is a companion policy guide designed to help health insurers make use of the results from a recent ICER evidence review and meeting of the New England Comparative Effectiveness Public Advisory Council (CEPAC) on "Controversies in the Management of Patients with Type 2 Diabetes."

CEPAC held its meeting on type 2 diabetes management on October 29, 2014 in Providence, RI. During the meeting, CEPAC voted on the comparative clinical effectiveness and value of different management approaches, and explored how best to apply the evidence to practice and policy with a distinguished Policy Expert Roundtable of patient advocates, clinical experts, and policy leaders from across New England.

This guide is intended to provide health insurers and policymakers with a series of action steps that can be taken to improve efficiency and quality of care. The content provided here is based on the published evidence as well as best practices recommended from subject matter experts during the CEPAC meeting. This guide is for informational purposes only, and it is not designed to replace professional medical advice.

Prevalence of Type 2 Diabetes

Based on extrapolations from national diabetes statistics, approximately 1.4 million adult residents of New England are living with type 2 diabetes.

Statewide Prevalence			
		National Diabetes Statistics	*Total*
Age	# Persons in New England	Diabetes Prevalence	*T2D Patients*
21-44	4,668,364	4.1%	181,833
45-64	4,196,389	16.2%	645,824
65+	2,172,048	25.9%	534,432
Total	11,036,801		***1,362,089***

For full calculations, view the appendix.

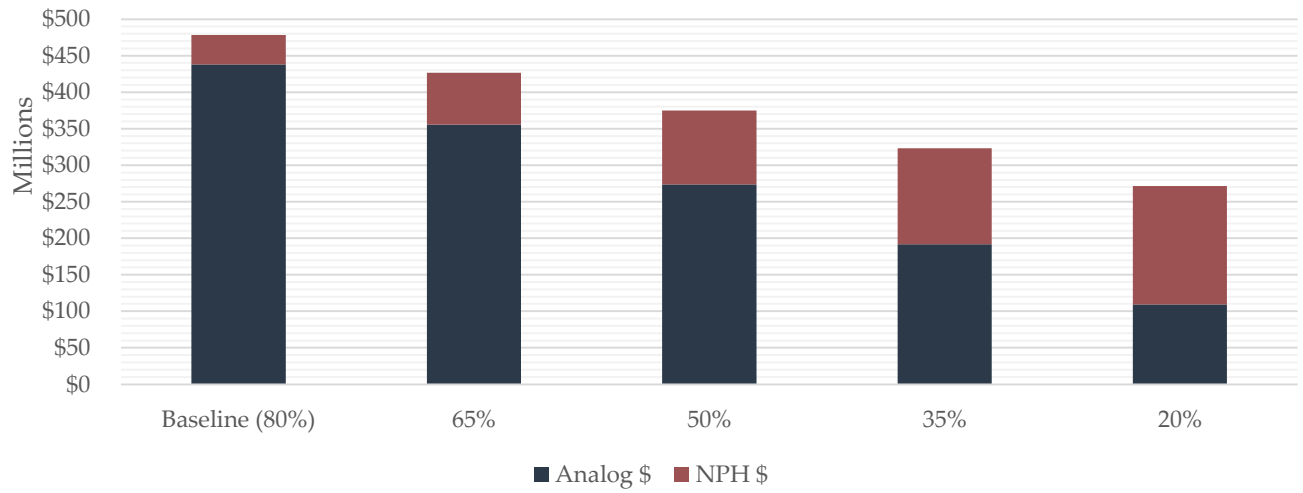
Insulin Choice

1. For patients requiring insulin, align patient education, clinical guidance, and coverage policies to encourage consideration of human insulin (NPH) as the initial choice instead of more expensive insulin analogs.

The available evidence suggests that most patients with type 2 diabetes can achieve equal levels of glycemic control with regular human insulin (NPH) as they can with more expensive analog formulations. NPH use does not result in higher levels of weight gain nor does it cause more adverse events, except for "nonsevere" hypoglycemia (i.e., symptomatic or nocturnal events that do not require third-party intervention). Given that NPH is much less expensive than insulin analogs, human insulin offers high value compared to long-acting analog alternatives. For a typical patient, average costs of NPH insulin are approximately $80 for 30 days at average wholesale price (AWP). Insulin analogs are nearly triple that amount, at approximately $220 AWP for a 30 day supply.

Insulin analogs are preferred for patients who have higher risks of significant hypoglycemia or those who require two insulin shots per day. But for many patients, NPH insulin will provide an equivalent balance of risks and benefits. Although approximately 80% of patients using insulin in the US are treated with insulin analogs, health systems such as the Veterans Affairs (VA) and the UK National Health Service succeed in treating a much higher proportion of patients with NPH insulin. The potential savings that could be achieved with increased use of NPH insulin are substantial, as shown in Figure 1 below.

Figure 1. Budgetary impact of shifts in the distribution of insulin analog vs. NPH insulin use in New England



Baseline use of insulin analogs is estimated to be 80% of all patients. If 65% of patients used insulin analogs, the savings would be approximately $50 million. With a further reduction to 50% of patients using insulin analogs, savings would reach over $100 million.

New England Budgetary Impact

Treating a higher proportion of patients with NPH insulin instead of an insulin analog can have significant potential economic benefit throughout New England. The information below provides cost savings information from a regional perspective. The table provides a summary of potential savings to New England as a whole as a greater proportion of patients use NPH insulin instead of analogs.

Insulin Use in New England

Approximately 205,000 New England residents living with type 2 diabetes use insulin, with 80% likely to be using an analog based on national data.

If an additional 30% of patients used NPH insulin instead of an analog, the region would save approximately **$103 million.**

Costs of Insulin Among Type 2 Diabetes Patients Using Insulin in New England (in millions of $)				
% of patients using analog	Total analog expenditure	Total human insulin expenditure	Total combined insulin expenditure	Change from current level
80%	$437.8	$40.5	$478.4	---
50%	$273.6	$101.3	$375	($103.4)
20%	$109.5	$162.2	$271.6	($206.5)

Assumptions: Dosing for an 89 kg individual (0.3 units/kg, 27 units), augmentation; pricing based on November NADAC price + 23.1% rebate. Full table available in the Appendix to this document.

Coverage Policies: Prior authorization and step-therapy requirements are potential mechanisms to direct clinicians and patients towards trying NPH first. Exemptions should be included in policies for patients with comorbid conditions, job conditions, or other factors that make frequent monitoring of blood glucose levels and two or more daily insulin injections difficult and would elevate the risk that nonsevere hypoglycemia would produce significant effects on health or quality of life. Policies should be flexible in design and application to ensure the ability to rapidly switch patients to insulin analogs if needed. Examples of language used by the VA and the UK National Health Service to support the use of NPH insulin are shown in the box below.

The US Veterans' Health Administration (VA) and the UK's National Health Service provide examples of policies that support the use of NPH insulin over as effective but more costly alternatives.

U.S. Veterans' Health Administration Guidelines:

Insulin glargine or detemir (insulin analogs) may be considered in the NPH insulin-treated patient with frequent or severe nocturnal hypoglycemia.

NICE (UK) Guidelines for insulin analogs:

Long-acting analogs should be considered only in patients who:

- Are unable to give themselves injections,
- Have frequent episodes of hypoglycemia that interfere with life
- Would otherwise need two insulin injections

If patients do not meet one or more criteria, NPH insulin should be used.

The NICE academic detailing aid provides prescribing and medication optimization messaging for healthcare personnel to support the use of NPH insulin.

Patient Education: Additional patient education can help reduce the perceived concerns regarding hypoglycemia and adherence with NPH. More targeted education instructing patients on how to prevent and manage hypoglycemia, and providing additional resources for self-education and support are key to patient success. Resources for this patient education are given below:

Resources to support patients in management of hypoglycemia

Diabetes self-management training is critical to patient success in managing diabetes.

The American Diabetes Association provides minimum standards for diabetes self-management education and support to guide appropriate patient education. Certified diabetes educators are also available to provide in-depth patient education. Additional information is available from the American Association of Diabetes Educators.

Educating patients to recognize and address symptoms of hypoglycemia can help reduce their risk while taking NPH insulin. The following resources provide patient information on how to safely manage blood sugar levels.

- **"What is low blood sugar?",** a guide from Lilly Diabetes
- **Explaining Blood Glucose,** a patient handout from the ADA
- **Managing and Preventing Hypoglycemia,** a patient handout from the Academy of Nutrition and Dietetics
- **Know the Symptoms: Hypoglycemia,** a graphic guide from the Wisconsin Dept. of Health

SECOND- AND THIRD-LINE TREATMENT OPTIONS

2. Encourage systems that promote initial use of high value treatment options before more costly or less proven alternatives.

Table 1. Costs of Select Second- and Third-Line Agents

Drug Class	Price for 30 days of treatment (based on average wholesale price estimates)
Sulfonylureas: First generation: chlorpropamide (Diabinese®), tolbutamide (Orinase®) Second generation: glipizide (Glucotrol®), glyburide (Micronase®), glimepiride (Amaryl®)	**$55**
GLP-1 receptor agonists: exenatide (Byetta®); exenatide extended-release (Bydureon®); liraglutide (Victoza®); dulaglutide (Trulicity®); albiglutide (Tanzeum®)	**$233**
DPP-4 inhibitors: sitagliptin (Januvia®); saxagliptin (Onglyza®); linagliptin (Tradjenta®); alogliptin (Nesina®)	**$326**

Source: Micromedex Healthcare Series. RED BOOK® Online. Greenwood Village, CO: Truven Health Analytics, 2014. http://truvenhealth.com/. Accessed May, 2014

For patients that have failed with metformin monotherapy, initial second-line therapy with sulfonylureas is a reasonable choice. Though GLP-1 receptor agonists may offer incremental clinical benefits related to reduced weight gain and incidence of non-severe hypoglycemia – benefits that will be of greater potential importance for some patients than others – the limited magnitude of these clinical benefits represent a "low value" given the high per-patient incremental cost of GLP-1 receptor agonists compared to sulfonylureas. The evidence is not adequate to demonstrate any clinical advantages of DPP-4 inhibitors over less-expensive sulfonylureas as second-line therapy. The boxes on the following page outline policies currently in use to limit unnecessary prescribing of more expensive, less proven drug classes. These policies can be used as examples in developing prior authorization policies.

Policies should allow enough flexibility to allow clinicians and patients to tailor treatment appropriately for specific patient needs. For instance, some patients will benefit more from GLP-1 receptor agonists as initial second-line therapy due to the drugs' positive effect on body weight. When developing policy, health plans and provider organizations must balance the mutual goals of maximizing health system value while creating an environment in which clinicians can provide individualized treatment as necessary without undue difficulty. The example policies provided on the following page contain provisions by which specific patient populations are able to access GLP-1 receptor agonists or DPP-4 inhibitors when appropriate, such as in cases of contraindication.

For patients who need additional therapy after metformin plus a sulfonylurea, the evidence suggests that NPH insulin or GLP-1 receptor agonists are reasonable choices, with NPH insulin representing the higher value option. GLP-1 receptor agonists produce less weight gain and a lower incidence of nonsevere hypoglycemia compared to NPH insulin, but the high per-patient additional cost makes GLP-1 receptor agonists a "low value" third-line therapy. Evidence is inadequate to demonstrate clinical advantages for DPP-4 inhibitors over less-expensive NPH insulin. The MassHealth and U.S. VA guidelines shown below provide examples of policies that encourage the use of insulin before DPP-4 inhibitors or GLP-1 receptor agonists.

MassHealth Prior Authorization Policy

Compared to other state Medicaid programs, MassHealth has a more restrictive prior authorization policy for DPP-4 inhibitors and GLP-1 receptor agonists.

Patients must meet all three criteria below before being eligible to try a medication from either drug class:

- Appropriate diagnosis of type 2 diabetes; AND
- Insufficient improvement with 90 days of metformin therapy, OR adverse event or contraindication to metformin; AND
- Insufficient improvement with 90 days of metformin combination therapy with sulfonylureas, pioglitazone, or insulin therapy, OR contraindication to all of these agents

Members can be exempt from prior authorization requirements if they have a history of pharmacy claims for the given medication for at least 90 of the past 120 days, or a history of type 2 diabetes and MassHealth pharmacy claims for a metformin combination for a total of 90 days within a six month time period.

Source: MassHealth Drug List

GLP-1 Receptor Agonist Prescribing Guidelines: U.S. Veterans' Health Administration

The U.S. Veterans' Health Administration limits patient eligibility for treatment with a GLP-1 receptor agonist.

To receive a prescription for a GLP-1 receptor agonist in combination with other oral agents, the following criteria must be met:

- Provider specializes in diabetes management
- Patient has type 2 diabetes
- Patient has not reached HbA1c goal with combinations of at least 2 oral hypoglycemic agents at the highest tolerated dose (this excludes patients with contraindications to sulfonylurea, metformin, or TZDs that would prevent them from using at least 2 of these agents in combination)
- Patient is not a good candidate for insulin

If a patient does not meet these requirements, a second-line regimen of metformin + sulfonylurea is recommended, except in cases of contraindication.

DPP-4 Inhibitor Prescribing Guidelines: U.S. Veterans' Health Administration

These guidelines support the use of metformin, sulfonylurea, and insulin before a DPP-4 inhibitor.

Patients may be considered for a DPP-4 inhibitor if the following criteria are met:

- ***Monotherapy:*** Patient has a contraindication to metformin or sulfonylurea
- ***Dual therapy:*** HbA1c goals are not met with monotherapy and patient has a contraindication to metformin and sulfonylurea
- ***Triple therapy:*** HbA1c goals are not met and the patient is not a good candidate for insulin, or has declined insulin therapy.

In all cases, current HbA1c levels should be <1% above the desired target. For HbA1c levels above this threshold, other therapies, such as insulin, should be considered.

New England Coverage Policies for Second- and Third-Line Treatments: Public Payers

	DPP-4 Inhibitors Januvia® Onglyza® Tradjenta® Nesina®	GLP-1 Receptor Agonists Byetta® Bydureon® Victoza® Trulicity® Tanzeum®	Insulin (Basal) Humulin N® Novolin N® Levemir® Lantus®	Insulin (Bolus) NovoLog® Apidra® Humalog® Humulin R (U-100® and U-500®) Novolin R®
CT	• Januvia and Onglyza covered.	• Byetta, Bydureon, and Victoza covered.	• Covered without restrictions	
MA	• **PA required:** patients must have inadequate response to or adverse event with metformin monotherapy and combination therapy, and have contraindication to or adverse event w/ insulin, sulfonylureas, and pioglitazone • QL apply	• **PA required:** patients must have inadequate response to or adverse event with metformin monotherapy and combination therapy, and have contraindication to or adverse event w/ insulin, sulfonylureas, and pioglitazone • QL apply	• All formulations covered without restriction with the exception of pens and cartridges, which require PA	
ME	• Januvia and Onglyza are covered in patients with history of metformin use for at least 60 days in previous 18 months • PA required for Tradjenta • PA and ST required for Nesina • QL apply	• ST and PA required: patients should first fail with all other available oral medications and insulin • QL apply	• Covered without restrictions, with the exception of some bolus formulations that require PA (Apidra, a rapid-acting analog, and Humulin R U-500, a concentrated form of short-acting human insulin).	
VT	• Januvia and Onglyza covered in patients who have failed with metformin • Nesina and Tradjenta require additional failure with preferred DPP-4 inhibitors • QL apply	• Covered for patients who are at least 18 years of age and have failed with metformin • PA required for Byetta and Bydureon • QL apply	• All formulations covered without restriction with the exception of Apidra, which requires PA.	
NH	• Januvia and Onglyza covered without restriction • PA required for Tradjenta and Nesina	• *Not included on PDL*	• At least one version of human and analog basal or bolus insulin is covered without restriction • PA required for some formulations	
RI	• Covered in patients with history of metformin or TZD use in previous 90 days • PA required for Onglyza and Nesina	• Covered in patients with history of metformin or TZD use in previous 90 days • PA required for Bydureon and Victoza	• Generally all formulations covered without restriction, with the exception of pens and cartridges, which require PA	

State Medicaid programs vary in their coverage of DPP-4 inhibitors and GLP-1 receptor agonists. Of the six states, Massachusetts and Maine have the most restrictive policies. MassHealth's PA criteria require patients to have tried metformin monotherapy as well as combination therapy with inadequate results for both DPP-1 inhibitors and GLP-1 receptor agonists. Maine is less restrictive with DPP-4 inhibitors, but more restrictive with GLP-1 receptor agonists, requiring patients to first fail with all other oral medications and insulin. Connecticut, however, is much less restrictive, covering at least some brands of each medication with no restrictions. New Hampshire also covers some brands of DPP-4 inhibitor with no restriction, though their GLP-1 receptor agonist policy could not be located. Vermont and Rhode Island have moderately restrictive policies, requiring just metformin monotherapy before trying either a DPP-1 inhibitor of a GLP-1 receptor agonist.

New England Coverage Policies for Second- and Third-Line Treatments: Private Payers

Private payers throughout New England have varying policies for coverage of GLP-1 receptor agonists and DPP-4 inhibitors. All payers cover most formulations of insulin with no restrictions, regardless of whether it is an insulin analog or a human formulation. For DPP-4 inhibitor coverage, BCBSMA, BCBSVT, and NHPRI have the more restrictive policies, requiring either step therapy or prior authorization criteria before patients are approved for any DPP-4 inhibitor. Other payers cover at least one formulation, if not all, with no restrictions. For GLP-1 receptor agonist coverage, BCBSVT, ConnectiCare, HPHC, and NHPRI all require either step therapy or prior authorization for coverage. THP covers all brands without restriction, while BCBSMA and BCBSRI cover at least one brand without restriction. The table below outlines the coverage policies of regional private payers.

	DPP-4 Inhibitors Januvia® Onglyza® Tradjenta® Nesina®	**GLP-1 Receptor Agonists** Byetta® Bydureon® Victoza® Trulicity® Tanzeum®	**Insulin (Basal)** Humulin N® Novolin N® Levemir® Lantus®	**Insulin (Bolus)** NovoLog® Apidra® Humalog® Humulin R (U-100® and U-500®) Novolin R®
Blue Cross Blue Shield MA (BCBS MA)	• ST and PA required (must fail with other oral medications and insulin) • Tier 2	• Byetta covered without restriction • PA required for Victoza Tier 2 and 3	• Covered without restrictions	
Blue Cross Blue Shield Rhode Island (BCBS RI)	• Januvia and Tradjenta are covered without restriction • PA required for Onglyza and Nesina • QL apply (details not provided) • Tier 2 or 3	• Byetta covered without restriction • Bydureon and Victoza require PA • QL apply (details not provided) • Tier 2 or 3	• All formulations covered without restriction with the exception of pens and cartridges, which require PA	
Blue Cross Blue Shield Vermont (BCBS VT)	• ST required (patients must fail with metformin) • QL apply to Januvia and Onglyza (details not provided) • Tier 2 or 3 *Nesina not listed*	• ST required (patients must fail with metformin) • QL apply to Byetta, Victoza (details not provided) • Tier 2 or 3 *Trulicity and Tanzeum not listed*	• Covered without restrictions, with the exception of some bolus formulations that require PA (Apidra, a rapid-acting analog, and Humulin R U-500, a concentrated form of short-acting human insulin).	
ConnectiCare	• Januvia and Tradjenta covered without restriction • ST required for Onglyza and Nesina • Tier 2 or 3	• ST and QL apply to Byetta, Bydureon, and Victoza; Tier 2 • PA and QL apply to Tanzeum; Tier 3	• All formulations covered without restriction with the exception of Apidra, which requires PA.	
Harvard Pilgrim Health Care (HPHC)	• ST required for Januvia, Nesina, and Onglyza; Tier 3 •Tradjenta covered without restriction; Tier 2	• ST required for Byetta, Bydureon, and Victoza; Tier 2 • ST and QL apply for Trulicity and Tanzeum (28 day supply); Tier 3	• At least one version of human and analog basal or bolus insulin is covered without restriction • PA required for some formulations	
Neighborhood Health Plan RI (NHPRI)	• PA required: must fail with metformin or sulfonylurea	• PA required: must fail with metformin or sulfonylurea	• Generally all formulations covered without restriction. • PA required for pens, cartridges	
Tufts Health Plan (THP)	• Covered without restriction (Onglyza and Nesina not listed) • Tier 2	• Covered without restriction • Tier 2 or 3	• Covered without restrictions • Tier 2	

3. As accountable care organizations and global payment systems become more prominent, payers should ensure funding that adequately supports the provision of team-based services. Integrated health care teams are essential to providing comprehensive management of type 2 diabetes and ensuring that different treatment approaches are feasible given each patient's unique circumstances. Nurse case managers, dieticians, diabetes educators, pharmacists, and community health workers play key roles in providing ongoing education, support, and monitoring for patients with type 2 diabetes. They can help transition patients across different therapies, monitor hypoglycemia, and educate and provide support to patients as treatment strategies become more complicated and patients have more options to consider. Adopting a multi-disciplinary care team approach allows for more opportunities to reach patients outside of the practice setting to increase education and better engage patients in their treatment choices.

According to the Joslin Diabetes Center, a successful care team may include:

• Diabetes physicians	• Certified Diabetes Educators
• Nurses	• Dietitians
• Exercise specialists	• Nurse Practitioners
• Mental Health Counselors	

For patients with more advanced disease, other specialists may be included, such as ophthalmologists, cardiologists, nephrologists, and podiatrists. Additional guidelines for building a care team are available from the National Diabetes Education Program.

Paying for team-based care:

Health plans may reimburse for team-based care either through supplementary per-member/per-month payments or through a global payment approach that reimburses provider groups for the full costs of treating diabetes, accounting for staffing resources and the unique needs of the patients served. Global payments provide practices with flexibility to determine how to organize the health team and which services should be delivered and by whom to optimize patient results. Global payments may also allow clinicians more flexibility to reserve time for care coordination, education, follow-up support, and other activities that take place outside of in-person physician visits.

Even as payment models move away from traditional fee-for-service (FFS) reimbursement, FFS continues to play an important role. In many cases, health plans can directly reimburse for services provided by diabetes self-management educators, community health workers, and other clinicians. In the short-term, exploring ways to fully reimburse team-based health through FFS may be important until provider organizations in the region fully adopt global payments. At present, provider groups may find it difficult to fully invest in team-based care for global payment patients and not get paid at all for the same services rendered in FFS patients.

Resources for Reimbursement of Diabetes Self Management Training Education	
Guide to Diabetes Self-Management Training Reimbursement	Indian Health Service
Diabetes Self-Management Education Reimbursement Toolkit	Centers for Medicare and Medicaid

New England: Team-Based Care

State-specific approaches to team-based care and resources to support management of type 2 diabetes

Programs exist throughout New England that provide team-based care approaches to diabetes. A few such programs are briefly described below. The table on the following page provides information about programs and resources throughout New England that can assist in the development of effective diabetes care. Click on the links to learn more.

Connecticut Program Example: Bridgeport Hospital Adult Diabetes Management Program

Bridgeport Hospital's Diabetes Education Center has been recognized for its diabetes education program since 1999. The center offers group classes in self-management from certified diabetes educators, covering topics such as glucose monitoring, physical activity, and goal setting. The center also offers individual nutritional therapy education, run by registered dieticians, that focuses on implementing small changes to lifestyle to help patients manage their disease. For more information about this program, visit their website or call (203) 336-7305.

Rhode Island Program Example: Hallett Center for Diabetes and Endocrinology

The Hallett Center is located at Rhode Island Hospital and offers multidisciplinary care for people with diabetes. The center employs a number of health care professionals across a broad range of specialties to address all aspects of a patient's diabetes care, including endocrinologists, nurses, and diabetes educators. Patients have access to services such as screenings, support groups, oversight of nutrition and weight management, medication management, and prevention and treatment of diabetes-related complications. The center offers both individual and group diabetes education programs, as well as opportunity for one-on-one appointments with a nurse educator, dietician, and pharmacist. Learn more about the Hallett Center here.

Massachusetts Program Example: Whittier Street Health Center

The Whittier Street Health Center, a NCQA recognized Patient-Centered Medical Home facility located in Boston, offers diabetes care to a diverse population of patients. Whittier is accredited by the ADA as a Center of Excellence in Diabetes Self-Management. The diabetes clinic offers care to individuals at all stages of disease and includes care by a physician, case manager, clinical pharmacist, and a certified diabetes educator/dietician. Every patient participates in an individualized care plan that involves diabetes self-management skill development and goal-setting. The center also offers diabetes group appointments, during which 8-10 patients with diabetes participate in 2 hour sessions on management on support. For more information on the Whittier Street program, visit their website.

New England: Team-Based Care

Use the links below to access addition information about region-wide efforts to manage diabetes in New England.

American Diabetes Association, New England Chapter	Programs and volunteer information for the local ADA chapter
TARGET Diabetes, MaineHealth	Find patient education, clinical tools, and other resources to help support diabetes management.
Maine Diabetes Self-Management Training Manual	This manual provides guidelines for implementing the Maine Diabetes-Self Management Training program
Living well with diabetes (NH HHS)	Learn about diabetes programs in New Hampshire
Joslin Diabetes Center	Current programs, research developments, and patient materials from the Joslin Diabetes Center
Materials from the Massachusetts Diabetes Prevention and Control Program	Find guidelines and patient education materials to support effective diabetes management
Diabetes Education Class Curriculum	A sample class curriculum from Connecticut's Midstate Medical Center Diabetes and Nutrition Center
ADA Connecticut Chapter	Learn about the American Diabetes Association's Connecticut-based initiatives
New Hampshire Guidelines for Diabetes Care	Find guidance from the NH DHHS on managing diabetes
Take Charge of Your Diabetes & Live Free!	Find resources for the people of New Hampshire from the NH Diabetes Coalition Access Work Group
Fletcher Allen's Diabetes Care Roadmap	A proposed roadmap to guide primary care physicians in delivering high quality, coordinated diabetes care
Vermont Department of Health Diabetes Prevention and Control	Diabetes resources from the state health department
Guide for Diabetes Care	A resource from the Vermont Department of Health to help patients keep track of office visits, lab work, and self-management activities
Resources from the RI Department of Health	Information and resources from the RI Department of Health
Rhode Island Diabetes State Plan	Read the state's plan for diabetes management from the RI Diabetes Council

FUTURE EVIDENCE AND RESEARCH NEEDS

4. Payers and policymakers should support the development of evidence and future research in the following areas:

- **Further study of insulin pumps and continuous glucose monitors is needed to understand if certain patient subpopulations with type 2 diabetes may benefit from these technologies.** For future research to be relevant, additional regulation may be required from the FDA since at present, devices change and are upgraded so frequently that conducting meaningful long-term studies is impossible. CEPAC members recognized the challenge to developing a robust evidence base for devices as it is more difficult to perform a blinded study and there may be issues regarding confounding.

- **Further research is needed to understand the heterogeneity of treatment effects, specifically for identifying patient subpopulations whose risk of significant hypoglycemia should lead to initial treatment with insulin analogs, GLP-1 receptor agonists, or DPP-4 inhibitors.** Many important patient subpopulations are excluded from clinical trials, so little is known at present about treatment effects in patient groups that are not well-studied.

- **The research community should develop study designs that reflect patient preferences and analyze treatment regimens that are feasible for patients to maintain.** Further studies should also be framed around more patient-centered questions, like the percent of patients that achieve reductions in HbA1c levels without experiencing an adverse event. Conceptualized this way, research will more helpfully inform treatment decisions by addressing the questions that matter most to patients.

- **Additional long-term studies are also needed that analyze primary rather than intermediate outcomes.** Patient and clinical communities want to know the effect new medications have on mortality, myocardial infarction, stroke, and other long term complications of diabetes (e.g. retinopathy, neuropathy). Evidence on long-term outcomes exists for sulfonylureas, but is still lacking for newer medications.

Appendix

The below tables show full calculations for cost-related information. Table 1 shows calculations for the total estimated type 2 diabetes population in New England, as well as the number of patients within this population estimated to be using any type of insulin. Table 2 compares costs of analog and human insulin. Table 3 highlights the costs of an episode of nocturnal hypoglycemia. Table 4 shows costs associated with insulin use among type 2 diabetes patients using insulin as the proportion of patients using an insulin analog instead of NPH insulin decreases.

New England

Table 1. Type 2 Diabetes Population Using Insulin in New England

Age	# Persons	National Diabetes Prevalence	Type 2 Diabetes Multiplier	Insulin Use	Estimate of T2D Patients on Insulin	*Estimate of Total T2D Patients*
20-44	4,668,364	4.1%	95.0%	15.1%	27,457	181,833
45-64	4,196,389	16.2%	95.0%	15.1%	97,519	645,824
65+	2,172,048	25.9%	95.0%	15.1%	80,699	534,432
Total	11,036,801				205,676	1,362,089

Table 2. Insulin Costs

Type	Per Unit	Per Day	Per Year
Analog	$0.27	$7.29	$2,660.85
Human	$0.10	$2.70	$985.50

Table 3. Cost of Nocturnal Hypoglycemia

Per Event	Event Frequency	Annual Cost
$55.16	1/mo	$661.92

Table 4. Treatment Costs at Varying Percentages of Analog vs. Human Insulin Use

Assumptions: Dosing for an 89 kg individual (0.3 units/kg, 27 units), augmentation; pricing based on November NADAC price + 23.1% rebate

Analog %	Analog $	Human $	Total $	Change
80%	$437,817,353	$40,538,644	$478,355,996	---
75%	$410,453,768	$50,673,305	$461,127,073	($17,228,924)
70%	$383,090,184	$60,807,966	$443,898,149	($34,457,847)
65%	$355,726,599	$70,942,627	$426,669,226	($51,686,771)
60%	$328,363,014	$81,077,288	$409,440,302	($68,915,694)
55%	$300,999,430	$91,211,948	$392,211,378	($86,144,618)
50%	$273,635,845	$101,346,609	$374,982,455	($103,373,542)
45%	$246,272,261	$111,481,270	$357,753,531	($120,602,465)
40%	$218,908,676	$121,615,931	$340,524,608	($137,831,389)
35%	$191,545,092	$131,750,592	$323,295,684	($155,060,312)
30%	$164,181,507	$141,885,253	$306,066,760	($172,289,236)
25%	$136,817,923	$152,019,914	$288,837,837	($189,518,160)
20%	$109,454,338	$162,154,575	$271,608,913	($206,747,083)