Confronting the value challenge in an integrated disease management model: an example from the Netherlands

On 1 January 2010, the Netherlands began a programme for the comprehensive management of diabetes, as the first among several disease areas to be part of a chronic disease management initiative. The Dutch Ministry of Health, Welfare and Sport and CZ Insurance developed the programme with the joint objectives of improving patient care and reducing the overall cost of care, by reducing complications and concentrating care provision with general practitioners.

The programme represents an integrated approach to diabetes care at the national level. Three factors distinguish this programme from the traditional approach to type 2 diabetes care:

- The organisation of care into provider groups centred on general practitioners (GPs)
- The movement to a lump-sum, per-patient system of reimbursement that will include the cost of medicines starting in 2011
- Making reimbursement based on provider groups meeting criteria for treatment and health outcomes.

The Dutch programme has several implications of interest to the Working Group and for the value-based management of type 2 diabetes. First, by tying reimbursement to health outcomes, the programme defines a set of indicators and measures for assessing the value of diabetes treatment to the payer. Due to significant overlap between the outcome measures set forth by the Dutch programme and surrogate measures of medicinal value as defined by the Working Group, the Dutch care standard might be used as a guide to value demonstration in drug development. In addition, by shifting the cost of prescribed medicines to the provider and limiting reimbursement to that required by treatment guidelines, the programme suggests an approach to controlling off-label usage of medicines.

Reimbursement on the basis of health outcomes

The programme requires doctors to structure the provision of care into provider groups centred on GPs. These groups will place the GP in a coordinating, case management role to draw upon diabetes care nurses, dieticians, physiotherapists and complications specialists. Provider groups will be reimbursed in the aggregate on a per-patient basis – rather than on a per-intervention basis – so long as they meet certain quality of care criteria (discussed below).

The level of reimbursement available for each patient will depend on that patient’s classification into one of five categories, depending on an estimate of the treatment they require. The categories are:

- New type 2 diabetes patient
- Patient controlled with oral anti-diabetics
- Patient requiring changeover to insulin therapy
- Patient controlled on insulin
Patient requiring extra consultations

The programme will reimburse patient care at a fixed budget that includes all aspects of diabetes treatment. As of December 2009, insurance companies were negotiating exact reimbursement rates for diabetes care with provider groups, which CZ Insurance experts expect to be in the €300-400 range per patient per year (this figure does not include the cost of medicines).

The programme is being implemented with a care standard that consists of approximately 16 indicators. CZ and other insurance companies, as the payers, will evaluate provider groups based on their aggregate performance along these parameters. CZ Insurance’s objective is to ensure that “the money is following the result. We are no longer paying for good behaviour or good thoughts [alone].”

Care standards as an expression of payer value

Because reimbursement in the new programme is based on provider groups’ performance along a multi-criteria care standard, that standard suggests the value drivers in the management of type 2 diabetes from the payer’s perspective. And, because the portion of the care standard related to indicators of health outcomes overlaps with the Shared Value Framework developed by the Working Group, the Dutch care standard might serve as a guide for demonstrating value in drug development.

Indicators of both process and outcome

The Dutch diabetes care standard contains both process and outcome indicators. Process indicators seek to ensure that patients receive the appropriate diagnostic, tracking and health maintenance interventions. They are based on the percentage of patients in a given provider group receiving each of the following:

- Annual BMI measurement
- Quarterly HbA1c measurement
- Quarterly office visits
- Annual fundus (eye) screening
- Diabetic foot screening
- Blood pressure measurement
- Smoking cessation advice

Outcome indicators seek to track the health benefits of treatment. They include:

- HbA1c (percentage < 7%)
- LDL cholesterol (percentage < 2,5 mmol/l)
- Blood pressure (percentage < 140 mmHg, systolic)
- BMI (percentage BMI < 25)
The overlap between the outcome indicators in the Dutch programme and the value indicators the Working Group developed for the assessment of type 2 diabetes medicines can provide clearer guidance for drug development. An industry participant found the inclusion of outcome measures compelling and remarked: “If I were to translate this into drug development, I would measure these four things in my active control group and present the data to [the payer].”

Surrogate versus hard outcome measures
Participants also noted that the care standard’s outcome measures are surrogates and debated whether at least one hard endpoint, amputations, warrants inclusion in the standard. The four outcome measures in place to assess the quality of care correspond in the Shared Value Framework the Group developed to surrogate measures of glycaemic control and control of cardiovascular risk factors. A medical expert remarked that the Dutch programme is lacking consideration of hard endpoints such as “retinopathy, myocardial infarction and amputation.” Participants acknowledged that “the outcomes gain is a long term gain” and such measures require “big populations.” However, they raised the possibility that amputations could be used as an early signal of hard outcomes, because “amputation is something you can put in that responds within 12 months.”

Calibrating performance expectations
Another set of comments concerned the appropriate performance expectation for outcome indicators that should be sufficient for full reimbursement. A medical expert with experience with a similar programme implemented by the U.S. Department of Veterans Affairs noted “you cannot meet all those [outcome] goals in 100% of people” and suggested that a more appropriate target for meeting the care standards is “70% to 80% of patients.” A fellow medical expert added that a BMI target of 25 or less is unrealistic. Several participants cautioned that an overly stringent standard for reimbursement would create perverse incentives for provider groups to exclude patients whose disease is more difficult to manage.

The Dutch programme as a way to control off-label prescribing
By 2011, the Netherlands will cease to reimburse diabetes medicines independently, rather increasing the per-patient reimbursement level to include the cost of medicines as well. Experts at CZ Insurance expect that the programme will set a fixed, per-patient reimbursement amount for all of the diabetes medicines required for treatment. If a GP prescribes medicines for a patient that cost more than this fixed amount, the excess cost will have to be borne by that GP’s care group.

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1 See U.S. Department of Veterans Affairs Primary Care Manual: Diabetes April, 2009 at http://www.hiv.va.gov/valhiv/page=pcm-206_diabetes5S3X.
CZ Insurance will seek to balance the pressure for cost control with the goal that patients receive the medicines deemed appropriate for them in the current treatment guidelines, regardless of price. As explained to the Group, “If in the standard it says that a certain group of patients has to get an expensive new medicine, then he gets that and in the group you have to prescribe that drug.” To ensure this is done equitably, CZ will consider increasing the portion of the lump-sum reimbursement allotted to medicines to account for increased costs from new, more expensive drugs required by the treatment standard.

According to a regulator participant, this arrangement represents “a sea change if you succeed with it.” He explained: “In the past we have always known as the regulatory community that when we give a label [that limited the use of a drug] nobody would follow that and the company hoped that it would sell much wider. Now the next step was that payers said it should only go to people who, say, are overweight with diabetes. [Still the concern is that] doctors prescribe it as they saw fit.” The novelty of the Dutch approach is that, by shifting the cost of prescribing to the provider, it raises the prospect that the payer “will effectively be in control and will ensure” that a medicine is only prescribed in accordance with treatment guidelines.