the DBL report

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An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

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Highlights of New Products Added

■ **GLUCAGON** (glucagon rDNA origin) (LIL) – is a product intended to replace Glucagon (animal source) that was recently discontinued by the manufacturer. The Committee noted that the cost of recombinant **GLUCAGON** was significantly higher than that of the animal source product. However, with no alternative product currently available on the market for the emergency treatment of severe hypoglycemia, the Committee reluctantly agreed that the recombinant form of **GLUCAGON** be added to the AHWDBL despite the substantive cost disparity compared to animal-source Glucagon.

■ **PARIET** (rabeprazole sodium) (JOI) – the 10mg and 20mg tablet formulations of this new proton pump inhibitor (PPI) were submitted for consideration. Following the Committee's review of the evidence provided, it was noted that there are no therapeutic advantages of **PARIET** vis-à-vis other PPIs currently listed on the AHWDBL; therefore, cost became the primary consideration in making a recommendation. As a result, the Committee recommended that only **PARIET 10 mg** should be added to the AHWDBL as it provided the most attractive cost savings. Specifically, **PARIET 10 mg** is priced at $0.65/tablet (or $1.30/2 x 10mg tablets), hence it is less expensive than Pariet 20mg priced at $1.90/tablet, as well as other PPIs currently listed on the AHWDBL.

■ **VALCYTE** (valganciclovir HCl) (HLR) – 450mg tablets are indicated for the treatment of cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome (AIDS). **VALCYTE** is a prodrug of ganciclovir, which is available on the AHWDBL as Cytovene in both an oral and IV formulation. Cytovene has a low oral bioavailability; therefore, the IV formulation is commonly used for both the induction and maintenance phases of treatment. Clinical studies showed that **VALCYTE** and Cytovene are comparable in terms of satisfactory patient responses. Therefore, the Committee recommended that **VALCYTE** be added via **Special Authorization** with the following criteria for coverage: "For the treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS)."

Highlights of Deferred Products

■ **DEXIRON** (iron dextran) (Luitpold) and **INFUFER** (iron dextran) (SAB) – are indicated for the treatment of iron deficiency in patients with documented iron deficiency in whom oral administration is unsatisfactory or impossible. The Committee acknowledged that these products are intended to replace the product, Jectofer, which has been discontinued by the manufacturer. The Committee expressed concern regarding the lack of data provided in iron deficient, but otherwise healthy individuals. In addition, it was noted that no pharmacokinetic data following intramuscular (IM) administration nor data to support IM use was provided in either of the submissions. Therefore, the Committee indicated that they required additional information prior to making a recommendation regarding the potential coverage of **DEXIRON** and **INFUFER** and recommended that these products be deferred pending the receipt and review of additional information from the respective manufacturers.

Devices Added to the AHWDBL as Restricted Benefits

- **PRIMEAIRE** (Methapharm) - is a portable, reusable, dual-valved holding device to be used with most metered dose inhalers. Evidence provided by the manufacturer indicates that drug delivery is improved when the spacing device is utilized as compared to the metered dose inhaler alone. The Committee noted that the price of this product is within the range of prices of spacing devices currently listed on the AWHDBL. Accordingly, the Committee recommended that **PRIMEAIRE** be granted a similar listing status. Hence, it was recommended that this product be made available as a **Restricted Benefit** with the following criteria for coverage: "Coverage is limited to one aerosol holding chamber per plan participant per year."

- **FACIAL MASKS FOR USE WITH PRIMEAIRE** (Methapharm) – There are four sizes of facial masks (pediatric, small, medium, large-adult) that are intended for use with the PrimeAire spacing device. As PrimeAire was recommended for addition to the AHWDBL, the **FACIAL MASKS** were recommended for addition as a **Restricted Benefit** with the following criteria for coverage: "Coverage is limited to one of each size (infant, pediatric, adult) aerosol holding chamber mask or chamber with mask per plan participant per year."

Highlights of Products Not Added

- **AMARYL** (glimepiride) (AVE) – 1 mg, 2 mg and 4 mg tablets were not recommended for addition to the AHWDBL, as they did not offer a cost and/or therapeutic advantage. Although **AMARYL** appeared unique in that it offered once daily dosing, the clinical evidence provided did not support a therapeutic advantage commensurate with the increased cost over sulfonylureas already available on the AHWDBL (e.g., glyburide, gliclazide).

- **ANDROGEL** (testosterone USP) (SLO) - 2.5 g/packet and 5 g/packet were not recommended for addition to the AHWDBL as they failed to offer a cost and/or therapeutic advantage. The Committee noted that there were no data provided to support effects on the symptoms of hypogonadism nor were there any data comparing **ANDROGEL** to Andriol or injectable testosterone. Furthermore, the Committee indicated that the cost of **ANDROGEL** was higher than that of Andriol and injectable testosterone. Hence, the Committee advised that insufficient evidence had been provided to support a therapeutic or economic benefit of **ANDROGEL** vis-à-vis other testosterone products currently listed on the AHWDBL.

- **DOVOBET** (calcipotriol & betamethasone dipropionate) (LEO) – the 50mcg/g & 0.5mg/g ointment was not recommended for addition as it does not offer a cost and/or therapeutic advantage. In making this recommendation, the Committee expressed concern that a fixed combination product such as **DOVOBET** does not allow for the titration of the steroid component. Specifically, the Committee noted that often patients with psoriasis use calcipotriol on a continuous basis and may alter their use of different steroids as needed (e.g., depending on severity, body area, etc). The use of **DOVOBET** may result in the continuous application of a potent steroid when it is not indicated. Furthermore, it was noted that the cost savings predicted by the manufacturer are largely based on the assumption that **DOVOBET** would be used once daily. Given that the individual components of this product are used twice daily, the Committee was skeptical that patients would alter their use of such agents to a once daily application.

- **LUMIGAN** (bimatoprost) (ALL) - 0.03% ophthalmic solution is indicated for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension who are intolerant or insufficiently responsive to another intraocular pressure lowering medication. Due to discrepancies in the data reported within the submission that could not be explained, the Committee advised that it could not be determined whether **LUMIGAN** had any therapeutic advantages over products currently listed on the AHWDBL. In addition, the Committee noted **LUMIGAN** was priced similarly to Xalatan ($0.31/drop vs. $0.32/drop, respectively) but was more expensive than Travatan ($0.24/drop). Accordingly, the Committee recommended that **LUMIGAN** not be added to the AHWDBL, as it fails to offer a cost and/or therapeutic advantage.

- **STARLIX** (nateglinide) (NOV) – 60 mg, 120 mg and 180 mg tablets are short-acting insulin secretagogues indicated for monotherapy and in combination with metformin to lower blood sugar in patients with Type 2 diabetes mellitus. Based on the data provided, the Committee noted that **STARLIX** is comparable to Gluconorm (repaglinide). In addition, the Committee indicated that head to head studies comparing the two agents would have been useful to ascertain the clinical significance of the reported differences in pharmacokinetics between these two agents. Although the Committee found the pricing of **STARLIX** to be favorable (identical price for each tablet regardless of strength), they indicated that the addition of **STARLIX** would not merit the projected incremental costs that would be incurred. Hence, the Committee recommended that **STARLIX** not be added to the AHWDBL as it failed to offer a cost and/or therapeutic advantage.