PostScriptExtra

NHS Greater Glasgow and Clyde

Pharmacological management of adult patients with type 2 diabetes, No. 23, November 2013

Appendix 1 – Pharmacology, licensed indications, and formulary status of antidiabetic medicines

Drug class: Biguanide
Name of medicine: Metformin

Pharmacology: Metformin lowers both basal and postprandial plasma glucose. It does not stimulate insulin secretion and therefore does not produce hypoglycaemia. Metformin may act via 3 mechanisms, reduction of hepatic glucose production by inhibiting gluconeogenesis and glycogenolysis in muscle, by increasing insulin sensitivity, improving peripheral glucose uptake and utilization and delay of intestinal glucose absorption. Metformin stimulates intracellular glycogen synthesis by acting on glycogen synthase. It also increases the transport capacity of all types of membrane glucose transporters (GLUTs) known to date. In clinical studies, use of metformin was associated with either a stable body weight or modest weight loss.

Licensed Indication(s)	Formulary status
Treatment of type 2 diabetes mellitus, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control. Metformin may be used as monotherapy or in combination with other oral antidiabetic agents or with insulin.	**Preferred list** **Restrictions:** Metformin powder for oral solution is restricted to patients who are unable to swallow the metformin tablets and should be used in preference to metformin oral solution. Metformin SR (Glucophage SR®) is non-Formulary.

Drug class: Sulfonylurea
Name of medicine: Gliclazide

Pharmacology: Gliclazide reduces blood glucose levels by stimulating insulin secretion from the pancreatic beta cells. Increase in postprandial insulin and C-peptide secretion persists after two years of treatment. In type 2 diabetics, gliclazide restores the first peak of insulin secretion in response to glucose and increases the second phase of insulin secretion. A significant increase in insulin response is seen in response to stimulation induced by a meal or glucose.

Licensed Indication(s)	Formulary status
Treatment of type 2 diabetes mellitus.	**Preferred list**

NB. All licensed indications in the table are applicable to adult patients with type 2 diabetes mellitus.
Licensing can change, therefore, always refer to the most up-to-date Summary of Product Characteristics via http://www.medicines.org.uk/emc/.
NHSGGC Formulary status can change, therefore, always refer to the GGC Prescribing website at www.ggcprescribing.org.uk for current status.

Drug class: Thiazolidinedione
Name of medicine: Pioglitazone

Pharmacology: Pioglitazone effects may be mediated by a reduction of insulin resistance. Pioglitazone appears to act via activation of specific nuclear receptors (peroxisome proliferator activated receptor gamma) leading to increased insulin sensitivity of liver, fat and skeletal muscle cells in animals. Treatment with pioglitazone has been shown to reduce hepatic glucose output and to increase peripheral glucose disposal in the case of insulin resistance.

Licensed Indication(s)	Formulary status
Second or third line treatment of type 2 diabetes mellitus: as **monotherapy** in patients (particularly overweight patients) inadequately controlled by diet and exercise for whom metformin is inappropriate because of contraindications or intolerance as **dual oral therapy** in combination with: metformin, with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin or a sulfonylurea, only in adult patients who show intolerance to metformin or for whom metformin is contraindicated, with insufficient glycaemic control despite maximal tolerated dose of monotherapy with a sulfonylurea. as **triple oral therapy** in combination with: metformin and a sulfonylurea, with insufficient glycaemic control despite dual oral therapy. Also indicated in **combination with insulin.**	**Preferred list** **Restrictions:** initiation is restricted to clinicians experienced in the treatment of diabetes. **Monotherapy**: is restricted to patients in whom consideration is otherwise being given to commencing insulin therapy. It is not recommended as monotherapy in any other group of patients. **Triple therapy**: in combination with metformin and a sulfonylurea is restricted to initiation and monitoring only by physicians experienced in the treatment of diabetes mellitus. Use in combination with insulin is restricted to specialist initiation.

Drug class: Dipeptidyl peptidase-4 (DPP-4) inhibitor
Name of medicine: Linagliptin

Pharmacology: Gliptins inhibit DPP-4 which is involved in the inactivation of GLP-1 (glucagon-like peptide-1) and GIP (glucose dependent insulinotropic polypeptide). GLP-1 and GIP are secreted at a low basal level throughout the day and levels rise immediately after meals. GLP-1 and GIP increase insulin biosynthesis and secretion from beta cells and GLP-1 lowers glucagon secretion from pancreatic alpha cells. The effects of GLP-1 and GIP are glucose dependent such that when blood glucose concentrations are low, stimulation of insulin release and suppression of glucagon secretion by GLP-1 are not observed. Gliptins are potent, selective inhibitors of DPP-4, and therefore increase insulin secretion in a glucose dependent manner and lower glucagon secretion which improves glucose homoeostasis with a reduced risk of hypoglycaemia.

Licensed Indication(s)	Formulary status
Treatment of type 2 diabetes mellitus. As **monotherapy:** in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to intolerance, or contraindicated due to renal impairment. as **combination therapy**: with metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control. With a sulfonylurea and metformin when diet and exercise plus dual therapy do not provide adequate glycaemic control. With insulin with or without metformin, when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.	**Total formulary** **Restrictions:** As **monotherapy** in patients for whom both metformin and sulfonylureas are inappropriate due to contradictions or intolerance**.** In combination with metformin when diet and exercise plus metformin alone does not provide adequate glycaemic control in patients for whom the addition of a sulfonylurea is inappropriate. As **combination therapy** with a sulfonylurea and metformin when diet and exercise plus dual therapy does not provide adequate glycaemic control**.** This class of medicines is not considered the most cost-effective choice when used as first-line therapy, and even when used as 2nd or 3rd line, they may only result in a modest reduction of HbA1c. In some situations, alternative therapy, such as insulin or GLP-1 analogue may be more appropriate**.**

NB. All licensed indications in the table are applicable to adult patients with type 2 diabetes mellitus.
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Drug class: Dipeptidyl peptidase-4 (DPP-4) inhibitor
Name of medicine: Saxagliptin
Pharmacology: Refer to linagliptin (above)

Licensed Indication(s)	Formulary status
Treatment of type 2 diabetes mellitus. As **monotherapy:** in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance. As **dual oral therapy in combination with:** metformin, when metformin alone, with diet and exercise, does not provide adequate glycaemic control, a sulfonylurea, when the sulfonylurea alone, with diet and exercise, does not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate, a thiazolidinedione, when the thiazolidinedione alone with diet and exercise, does not provide adequate glycaemic control in patients for whom use of a thiazolidinedione is considered appropriate. As **triple oral therapy in combination with**: metformin plus a sulfonylurea when this regimen alone, with diet and exercise, does not provide adequate glycaemic control. **Also in combination with insulin** (with or without metformin), when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.	**Total formulary** **Restrictions:** restricted to use in combination with metformin when a sulfonylurea is contraindicated or not tolerated. The use in combination with insulin is not recommended for use by SMC and is non-Formulary. This class of medicines are not considered the most cost-effective choice when used as first-line therapy, and even when used as 2nd or 3rd line, they may only result in a modest reduction of HbA1c. In some situations, alternative therapy, such as insulin or GLP-1 analogue may be more appropriate.

Drug class: Dipeptidyl peptidase-4 (DPP-4) inhibitor
Name of medicine: Sitagliptin
Pharmacology: Refer to linagliptin (above)

Licensed Indication(s)	Formulary status
Treatment of type 2 diabetes mellitus. As **monotherapy:** in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance. As **dual oral therapy in combination with:** metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control, a sulfonylurea when diet and exercise plus maximal tolerated dose of a sulfonylurea alone do not provide adequate glycaemic control and when metformin is inappropriate due to contraindications or intolerance, a thiazolidinedione when use of a thiazolidinedione is appropriate and when diet and exercise plus the thiazolidinedione alone do not provide adequate glycaemic control. As **triple oral therapy in combination with:** a sulfonylurea and metformin when diet and exercise plus dual therapy do not provide adequate glycaemic control, a thiazolidinedione and metformin when use of a thiazolidinedione is appropriate and when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control. **Also in combination with insulin** (with or without metformin) when diet and exercise plus stable dose of insulin do not provide adequate glycaemic control.	**Total formulary** **Restrictions:** monotherapy is restricted to patients for whom both metformin and sulfonylureas are inappropriate due to contraindications or intolerance. Combination with a sulfonylurea is restricted to patients in whom metformin is contraindicated or not tolerated. Combination with both metformin and a sulfonylurea (i.e. triple therapy) is restricted to patients who are inadequately controlled on their respective maximal tolerated doses of metformin and sulfonylurea. This class of medicines are not considered the most cost-effective choice when used as first-line therapy, and even when used as 2nd or 3rd line, they may only result in a modest reduction of HbA1c. In some situations, alternative therapy, such as insulin or GLP-1 analogue may be more appropriate.

NB. All licensed indications in the table are applicable to adult patients with type 2 diabetes mellitus.
Licensing can change, therefore, always refer to the most up-to-date Summary of Product Characteristics via http://www.medicines.org.uk/emc/.
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Drug class: Dipeptidyl peptidase-4 (DPP-4) inhibitor
Name of medicine: Vildagliptin
Pharmacology: Refer to linagliptin (above)

Licensed Indication(s)	Formulary status
Treatment of type 2 diabetes mellitus. As **monotherapy:** in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance. As **dual oral therapy in combination with:** metformin, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin, a sulfonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose of a sulfonylurea and for whom metformin is inappropriate due to contraindications or intolerance, a thiazolidinedione, in patients with insufficient glycaemic control and for whom the use of a thiazolidinedione is appropriate. As **triple oral therapy in combination with:** a sulfonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control. **Also in combination with insulin** (with or without metformin) when diet and exercise plus a stable dose of insulin do not provide adequate glycaemic control.	**Total formulary** **Restrictions:** use as monotherapy is restricted to use in patients for whom both metformin and sulfonylureas are inappropriate due to contraindications or intolerance use in combination with metformin or a sulfonylurea for patients with insufficient glycaemic control despite maximum tolerated dose of monotherapy with metformin or a sulfonylurea. All other licensed indications remain non-Formulary. This class of medicines are not considered the most cost-effective choice when used as first-line therapy, and even when used as 2nd or 3rd line, they may only result in a modest reduction of HbA1c. In some situations, alternative therapy, such as insulin or GLP-1 analogue may be more appropriate.

Drug class: Alpha glucosidase inhibitor
Name of medicine: Acarbose
Pharmacology: Acarbose exerts its activity in the intestinal tract. The action of acarbose is based on the competitive inhibition of intestinal enzymes (α-glucosidases) involved in the degradation of disaccharides, oligosaccharides, and polysaccharides. This leads to a dose-dependent delay in the digestion of these carbohydrates. Glucose derived from these carbohydrates is released and taken up into the blood more slowly. In this way, acarbose reduces the postprandial rise in blood glucose, thus reducing blood glucose fluctuations.

Licensed Indication(s)	Formulary status
Acarbose is recommended for the treatment of non-insulin dependent diabetes mellitus in patients inadequately controlled on diet alone, or on diet and oral hypoglycaemic agents.	**Total formulary** **Restrictions:** restricted to specialist initiation. Restricted to clinicians experienced in treating diabetes. Acarbose is restricted to use in patients refractory or intolerant to treatment with metformin.

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Drug class: Selective and reversible inhibitor of sodium-glucose co-transporter 2 (SGLT2)

Name of medicine: Dapagliflozin

Pharmacology: Dapagliflozin is a highly potent, selective and reversible inhibitor of SGLT2. SGLT2 is the predominant transporter responsible for reabsorption of glucose from the glomerular filtrate back into the circulation. Dapagliflozin improves both fasting and post-prandial plasma glucose levels by reducing renal glucose reabsorption leading to urinary glucose excretion. This glucose excretion (glucuretic effect) is observed after the first dose, is continuous over the 24-hour dosing interval and is sustained for the duration of treatment. Dapagliflozin does not impair normal endogenous glucose production in response to hypoglycaemia. Dapagliflozin acts independently of insulin secretion and insulin action.

Licensed Indication(s)	Formulary status
Treatment of type 2 diabetes mellitus to improve glycaemic control as: **Monotherapy:** When diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance. **Add-on combination therapy:** In combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.	**Total formulary** **Restrictions:** restricted to initiation by clinicians experienced in the management of diabetes as dual therapy in combination with metformin, when metformin alone with diet and exercise does not provide adequate glycaemic control and a sulfonylurea is inappropriate.

Drug class: Glucagon-like peptide-1 (GLP-1) agonist

Name of medicine: Exenatide

Pharmacology: The GLP-1 agonists bind to and activate the known human GLP-1 receptor *in vitro*, and their mechanism of action is mediated by cyclic AMP and/or other intracellular signalling pathways. The GLP-1 agonists stimulate insulin secretion from pancreatic beta cells in a glucose-dependent manner. They also suppress glucagon secretion in a glucose-dependent manner which is inappropriately elevated in type 2 diabetes. Therefore when blood glucose is high, insulin secretion is stimulated and glucagon secretion is inhibited. Conversely, during hypoglycaemia, the GLP-1 agonists diminish insulin secretion and do not impair glucagon secretion. The GLP-1 agonists slow gastric emptying, thereby reducing the rate at which meal-derived glucose appears in the circulation and may reduce body weight by mechanisms involving reduced hunger and lowered energy intake.

Licensed Indication(s)	Formulary status
Twice daily preparation (Byetta®): Treatment of type 2 diabetes mellitus **in combination with:** metformin, sulfonylureas, thiazolidinediones, metformin and a sulfonylurea, metformin and a thiazolidinedione in adults who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies. Also indicated as **adjunctive therapy to basal insulin** with or without metformin and/or pioglitazone in adults who have not achieved adequate glycaemic control with these agents. **Once weekly preparation (Bydureon®):** Treatment of type 2 diabetes mellitus in combination with: metformin, sulfonylurea, thiazolidinedione, metformin and sulfonylurea, metformin and thiazolidinedione in adults who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.	**Total formulary** **Restrictions:** Once weekly preparation is restricted to specialist initiation for the third line treatment of type-2 diabetes in combination with other agents. The twice daily preparation is restricted to specialist initiation as an alternative for patients who have failed treatment on metformin and/or sulfonylureas and in whom insulin would be the next treatment option. Use in combination with metformin and pioglitazone is restricted to specialist initiation and as a third-line pre-insulin treatment option. Adjunctive therapy to basal insulin with or without metformin and/or pioglitazone is restricted to specialist initiation.

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Drug class: Glucagon-like peptide-1 (GLP-1) agonist
Name of medicine: Liraglutide
Pharmacology: Refer to exenatide (above)

Licensed Indication(s)	Formulary status
Treatment of type 2 diabetes mellitus to achieve glycaemic control: **In combination with:** metformin or a sulfonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin or sulfonylurea. **In combination with:** metformin and a sulfonylurea or metformin and a thiazolidinedione in patients with insufficient glycaemic control despite dual therapy.	**Total formulary** **Restrictions:** restricted to specialist initiation as a third-line antidiabetic agent in combination with metformin and a sulfonylurea or metformin and a thiazolidinedione.

Drug class: Glucagon-like peptide-1 (GLP-1) agonist
Name of medicine: Lixisenatide
Pharmacology: Refer to exenatide (above)

Licensed Indication(s)	Formulary status
Indicated for the treatment of type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control.	**Total formulary** **Restrictions:** The treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control is included in the GGC Adult Formulary for the indication in question is restricted to specialist initiation as a third-line agent, either in combination with metformin and a sulfonylurea or metformin and a thiazolidinedione, or as adjunctive therapy to basal insulin in patients for whom a glucagon-like protein 1 (GLP-1) agonist is appropriate.

Combination Preparations

Drug class: Biguanide/thiazolidinedione
Name of medicine: Competact® (metformin/pioglitazone)
Pharmacology: Refer to pharmacology of individual components.

Licensed Indication(s)	Formulary status
Treatment of type 2 diabetes mellitus, particularly overweight patients, who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of oral metformin alone.	**Total formulary** **Restrictions:** restricted to initiation by physicians experienced in the treatment of diabetes mellitus for patients who cannot be treated or controlled with a sulfonylurea in combination with metformin. Combination preparations are further restricted to use only in those patients who have demonstrable compliance issues with the separate constituents.

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NHSGGC Formulary status can change, therefore, always refer to the GGC Prescribing website at www.ggcprescribing.org.uk for current status.

Drug class: Biguanide/DPP-4 inhibitor
Name of medicine: Janumet® (metformin/sitagliptin)
Pharmacology: Refer to pharmacology of individual components.

Licensed Indication(s)	Formulary status
Treatment of type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control in patients inadequately controlled on their maximal tolerated dose of metformin alone or those already being treated with the combination of sitagliptin and metformin. Indicated in combination with a sulfonylurea or thiazolidinedione (**triple combination therapy**) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a sulfonylurea or thiazolidinedione. Also indicated as **add-on to insulin** as an adjunct to diet and exercise to improve glycaemic control in patients when stable dose of insulin and metformin alone are inadequate.	**Total formulary** **Restrictions:** restricted to use in patients for whom a combination of sitagliptin and metformin is an appropriate choice of therapy and only when the addition of a sulfonylurea to metformin monotherapy is not appropriate. Combination preparations are further restricted to use only in those patients who have demonstrable compliance issues with the separate constituents. NB. For sitagliptin: This class of medicines are not considered the most cost-effective choice when used as first-line therapy, and even when used as 2nd or 3rd line, they may only result in a modest reduction of HbA1c. In some situations, alternative therapy, such as insulin or GLP-1 analogue may be more appropriate.

Drug class: Biguanide/DPP-4 inhibitor
Name of medicine: Eucreas® (metformin/vildagliptin)
Pharmacology: Refer to pharmacology of individual components.

Licensed Indication(s)	Formulary status
Treatment of type 2 diabetes mellitus in patients who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of oral metformin alone or who are already treated with the combination of vildagliptin and metformin. Indicated in combination with a sulfonylurea (i.e. **triple combination therapy**) as an adjunct to diet and exercise in patients inadequately controlled with metformin and a sulfonylurea. Also indicated in **triple combination therapy with insulin** as an adjunct to diet and exercise to improve glycaemic control in patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control.	**Total formulary** **Restrictions:** restricted to use only when the addition of a sulfonylurea is not appropriate for patients with insufficient glycaemic control despite maximum tolerated dose of monotherapy with metformin. All other licensed indications remain non-Formulary. Combination preparations are further restricted to use only in those patients who have demonstrable compliance issues with the separate constituents. NB. For vildagliptin: This class of medicines are not considered the most cost-effective choice when used as first-line therapy, and even when used as 2nd or 3rd line, they may only result in a modest reduction of HbA1c. In some situations, alternative therapy, such as insulin or GLP-1 analogue may be more appropriate.

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Drug class: Biguanide/DPP-4 inhibitor
Name of medicine: Jentadueto® (metformin/linagliptin)
Pharmacology: Refer to pharmacology of individual components.

Licensed Indication(s)	Formulary status
Treatment of type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control in patients inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of linagliptin and metformin. Indicated in combination with a sulfonylurea (i.e. **triple combination therapy**) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a sulfonylurea.	**Total formulary** **Restrictions:** restricted to use in patients for whom a combination of linagliptin and metformin is an appropriate choice of therapy and these fixed-doses are considered appropriate and where there is demonstrable compliance issues with the separate constituents. NB. For linagliptin: This class of medicines is not considered the most cost-effective choice when used as first-line therapy, and even when used as 2nd or 3rd line, they may only result in a modest reduction of HbA1c. In some situations, alternative therapy, such as insulin or GLP-1 analogue may be more appropriate.

Drug class: Biguanide/DPP-4 inhibitor
Name of medicine: Komboglyze® (metformin/saxagliptin)
Pharmacology: Refer to pharmacology of individual components.

Licensed Indication(s)	Formulary status
Indicated as an adjunct to diet and exercise to improve glycaemic control in patients with type 2 diabetes mellitus inadequately controlled on their maximally tolerated dose of metformin alone or those already being treated with the combination of saxagliptin and metformin as separate tablets. Also indicated in combination with insulin (ie, triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in patients with type 2 diabetes mellitus when insulin and metformin alone do not provide adequate glycaemic control. Also indicated in combination with a sulfonylurea (i.e., triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in patients with type 2 diabetes mellitus when the maximally tolerated dose of both metformin and the sulfonylurea does not provide adequate glycaemic control.	**Total formulary** **Restrictions:** restricted to use in patients for whom a combination of saxagliptin and metformin is an appropriate choice of therapy and only when the addition of sulfonylureas to metformin monotherapy is not appropriate. Combination preparations are further restricted to use only in those patients who have demonstrated compliance issues with the separate constituents NB. For saxagliptin: This class of medicines are not considered the most cost-effective choice when used as first-line therapy, and even when used as 2nd or 3rd line, they may only result in a modest reduction of HbA1c. In some situations, alternative therapy, such as insulin or GLP-1 analogue may be more appropriate.

References

NHS Greater Glasgow & Clyde Formulary (accessed via www.ggcprescribing.org.uk)
Manufacturer's Summary of Product Characteristics (SPC) for all agents available at http://www.medicines.org.uk/emc/

NB. All licensed indications in the table are applicable to adult patients with type 2 diabetes mellitus.
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