

Texas Prior Authorization Program Clinical Edit Criteria

Drug/Drug Class

Byetta (Exenatide Injection)

Clinical Edit Information Included in this Document

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical edit
 - **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical edit criteria rules
 - **Logic diagram:** a visual depiction of the clinical edit criteria logic
 - **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes); provided when applicable
 - **References:** clinical publications and sources relevant to this clinical edit
- Note:** Click the hyperlink to navigate directly to that section.

Revision Notes

- Added a new section to specify the drugs requiring prior authorization
- In the “Clinical Edit Criteria Supporting Tables” section, revised tables to specify the diagnosis codes pertinent to steps 2 and 4 of the logic diagram
- In the “Clinical Edit Criteria Supporting Tables” section, revised tables to specify the drug names and GCNs pertinent to steps 3 and 8 of the logic diagram
- In the “Clinical Edit Criteria Supporting Tables” section, revised tables to specify the procedure codes pertinent to steps 5 and 6 of the logic diagram



Byetta (Exenatide Injection)

Drugs Requiring Prior Authorization

Drugs Requiring Prior Authorization	
Label Name	GCN
BYETTA 5 MCG DOSE PEN INJ	24613
BYETTA 10 MCG DOSE PEN INJ	24614



Byetta (Exenatide Injection)

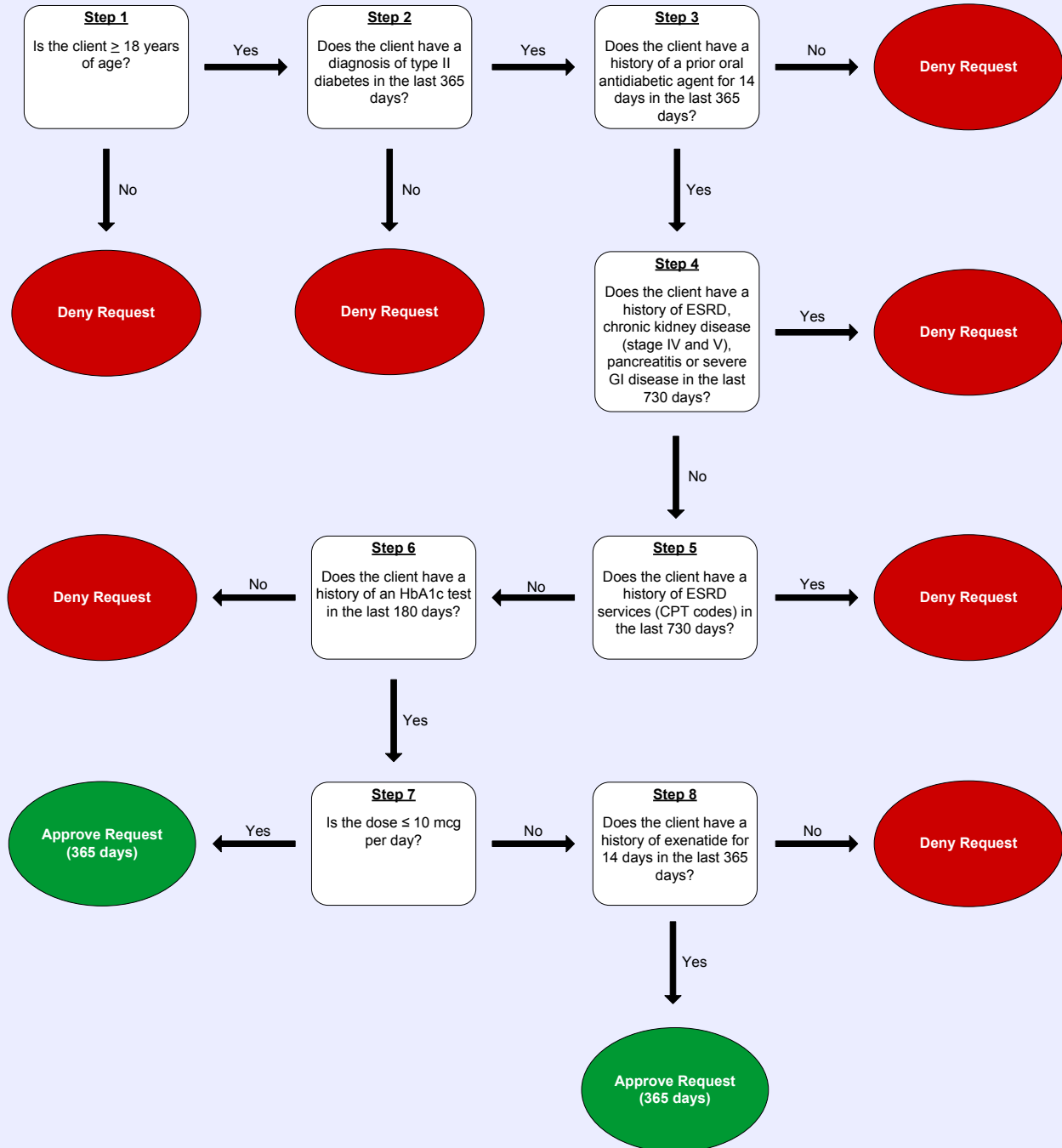
Clinical Edit Criteria Logic

1. Is the client greater than or equal to (\geq) 18 years of age?
 Yes (Go to #2)
 No (Deny)
2. Does the client have a diagnosis of type II diabetes in the last 365 days?
 Yes (Go to #3)
 No (Deny)
3. Does the client have a history of a prior oral antidiabetic agent for 14 days in the last 365 days?
 Yes (Go to #4)
 No (Deny)
4. Does the client have a history of ESRD, chronic kidney disease (stage IV and V), pancreatitis, or severe GI disease in the last 730 days?
 Yes (Deny)
 No (Go to #5)
5. Does the client have a history of ESRD services (CPT codes) in the last 730 days?
 Yes (Deny)
 No (Go to #6)
6. Does the client have a history of an HbA1c test in the last 180 days?
 Yes (Go to #7)
 No (Deny)
7. Is the dose less than or equal to (\leq) 10 mcg per day?
 Yes (Approve – 365 days)
 No (Go to #8)
8. Does the client have a history of exenatide for 14 days in the last 365 days?
 Yes (Approve – 365 days)
 No (Deny)



Byetta (Exenatide Injection)

Clinical Edit Criteria Logic Diagram





Byetta (Exenatide Injection)

Clinical Edit Criteria Supporting Tables

Step 2 (diagnosis of type II diabetes) Required diagnosis: 1 Look back timeframe: 365 days	
ICD-9 Code	Description
25000	DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
25002	DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
25010	DIABETES WITH KETOACIDOSIS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
25012	DIABETES WITH KETOACIDOSIS, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
25020	DIABETES WITH HYPEROSMOLARITY, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
25022	DIABETES WITH HYPEROSMOLARITY, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
25030	DIABETES WITH OTHER COMA, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
25032	DIABETES WITH OTHER COMA, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
25040	DIABETES WITH RENAL MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
25042	DIABETES WITH RENAL MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
25050	DIABETES WITH OPHTHALMIC MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
25052	DIABETES WITH OPHTHALMIC MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE UNCONTROLLED
25060	DIABETES WITH NEUROLOGICAL MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
25062	DIABETES WITH NEUROLOGICAL MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
25070	DIABETES WITH PERIPHERAL CIRCULATORY DISORDERS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
25072	DIABETES WITH PERIPHERAL CIRCULATORY DISORDERS, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
25080	DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
25082	DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE UNCONTROLLED

Step 2 (diagnosis of type II diabetes)	
Required diagnosis: 1	
Look back timeframe: 365 days	
ICD-9 Code	Description
25090	DIABETES WITH UNSPECIFIED COMPLICATION, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
25092	DIABETES WITH UNSPECIFIED COMPLICATION, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED

Step 3 (history of oral antidiabetic agent)	
Required quantity: 1	
Look back timeframe: 365 days	
Label Name	GCN
ACARBOSE 25 MG TABLET	08070
ACARBOSE 50 MG TABLET	02319
ACARBOSE 100 MG TABLET	02318
ACTOPLUS MET 15 MG-500 MG TAB	25444
ACTOPLUS MET 15 MG-850 MG TAB	25445
ACTOPLUS MET XR 15-1,000 MG TB	28620
ACTOPLUS MET XR 30-1,000 MG TB	28622
ACTOS 15 MG TABLET	92991
ACTOS 30 MG TABLET	93001
ACTOS 45 MG TABLET	93011
AMARYL 1 MG TABLET	05830
AMARYL 2 MG TABLET	05832
AMARYL 4 MG TABLET	05833
AVANDAMET 2 MG-500 MG TABLET	91742
AVANDAMET 2 MG-1,000 MG TAB	20313
AVANDAMET 4 MG-500 MG TABLET	91743
AVANDAMET 4 MG-1,000 MG TABLET	20314
AVANDARYL 4 MG-1 MG TABLET	26125
AVANDARYL 4 MG-2 MG TABLET	26126
AVANDARYL 4 MG-4 MG TABLET	26127
AVANDARYL 8 MG-2 MG TABLET	98489
AVANDARYL 8 MG-4 MG TABLET	97648
AVANDIA 2 MG TABLET	93193
AVANDIA 4 MG TABLET	93203
AVANDIA 8 MG TABLET	93363
CHLORPROPAMIDE 100 MG TABLET	05731
CHLORPROPAMIDE 250 MG TABLET	05732

Step 3 (history of oral antidiabetic agent)	
Required quantity: 1	
Look back timeframe: 365 days	
Label Name	GCN
DIABETA 1.25 MG TABLET	05710
DIABETA 2.5 MG TABLET	05711
DIABETA 5 MG TABLET	05712
DUETACT 30-2 MG TABLET	97181
DUETACT 30-4 MG TABLET	97180
FORTAMET ER 500 MG TABLET	21832
FORTAMET ER 1,000 MG TABLET	21831
GLIMEPIRIDE 1 MG TABLET	05830
GLIMEPIRIDE 2 MG TABLET	05832
GLIMEPIRIDE 4 MG TABLET	05833
GLIPIZIDE 5 MG TABLET	10840
GLIPIZIDE 10 MG TABLET	10841
GLIPIZIDE ER 2.5 MG TABLET	50638
GLIPIZIDE ER 5 MG TABLET	10844
GLIPIZIDE ER 10 MG TABLET	10843
GLIPIZIDE XL 2.5 MG TABLET	50638
GLIPIZIDE XL 5 MG TABLET	10844
GLIPIZIDE XL 10 MG TABLET	10843
GLIPIZIDE-METFORMIN 2.5-250 MG	18366
GLIPIZIDE-METFORMIN 2.5-500 MG	18367
GLIPIZIDE-METFORMIN 5-500 MG	18368
GLUCOPHAGE 500 MG TABLET	10810
GLUCOPHAGE 850 MG TABLET	10811
GLUCOPHAGE 1,000 MG TABLET	10857
GLUCOPHAGE XR 500 MG TAB	89863
GLUCOPHAGE XR 750 MG TAB	19578
GLUCOTROL 5 MG TABLET	10840
GLUCOTROL 10 MG TABLET	10841
GLUCOTROL XL 2.5 MG TABLET	50638
GLUCOTROL XL 5 MG TABLET	10844
GLUCOTROL XL 10 MG TABLET	10843
GLUCOVANCE 2.5-500 MG TABLET	92889
GLUCOVANCE 5-500 MG TABLET	89879
GLUMETZA ER 500 MG TABLET	97061
GLUMETZA ER 1,000 MG TABLET	97067
GLYBURIDE 1.25 MG TABLET	05710

Step 3 (history of oral antidiabetic agent)	
Required quantity: 1	
Look back timeframe: 365 days	
Label Name	GCN
GLYBURIDE 2.5 MG TABLET	05711
GLYBURIDE 5 MG TABLET	05712
GLYBURIDE MICRO 1.5 MG TAB	05713
GLYBURIDE MICRO 3 MG TABLET	05714
GLYBURIDE MICRO 6 MG TABLET	05715
GLYBURIDE-METFORMIN 2.5-500 MG	92889
GLYBURIDE-METFORMIN 5-500 MG	89879
GLYNASE 1.5 MG PRESTAB	05713
GLYNASE 3 MG PRESTAB	05714
GLYNASE 6 MG PRESTAB	05715
GLYSET 25 MG TABLET	95252
GLYSET 50 MG TABLET	95253
GLYSET 100 MG TABLET	95254
JANUMET 50-500 MG TABLET	98306
JANUMET 50-1,000 MG TABLET	98307
JANUVIA 25 MG TABLET	97398
JANUVIA 50 MG TABLET	97399
JANUVIA 100 MG TABLET	97400
KOMBIGLYZE XR 2.5-1,000 MG TAB	29225
KOMBIGLYZE XR 5-500 MG TABLET	29118
KOMBIGLYZE XR 5-1,000 MG TAB	29224
METAGLIP 2.5-250 MG TABLET	18366
METAGLIP 2.5-500 MG TABLET	18367
METFORMIN HCL 500 MG TABLET	10810
METFORMIN HCL 850 MG TABLET	10811
METFORMIN HCL 1,000 MG TABLET	10857
METFORMIN HCL ER 500 MG TABLET	89863
METFORMIN HCL ER 750 MG TABLET	19578
NATEGLINIDE 60 MG TABLET	12277
NATEGLINIDE 120 MG TABLET	34027
ONGLYZA 2.5 MG TABLET	27393
ONGLYZA 5 MG TABLET	27394
PRANDIMET 1 MG-500 MG TABLET	16084
PRANDIMET 2 MG-500 MG TABLET	16085
PRANDIN 0.5 MG TABLET	26311
PRANDIN 1 MG TABLET	26312

Step 3 (history of oral antidiabetic agent)	
Required quantity: 1	
Look back timeframe: 365 days	
Label Name	GCN
PRANDIN 2 MG TABLET	26313
PRECOSE 25 MG TABLET	08070
PRECOSE 50 MG TABLET	02319
PRECOSE 100 MG TABLET	02318
RIOMET 500 MG/5 ML SOLUTION	20808
STARLIX 60 MG TABLET	12277
STARLIX 120 MG TABLET	34027
TOLAZAMIDE 250 MG TABLET	05741
TOLAZAMIDE 500 MG TABLET	05742
TOLBUTAMIDE 500 MG TABLET	05724

Step 4 (diagnosis of ESRD, CKD, pancreatitis, or severe GI disease)	
Required diagnosis: 1	
Look back timeframe: 730 days	
ICD-9 Code	Description
40311	HYPERTENSIVE CHRONIC KIDNEY DISEASE, BENIGN, WITH CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
40391	HYPERTENSIVE CHRONIC KIDNEY DISEASE, UNSPECIFIED, WITH CHRONIC KIDNEY DISEASE STAGE V OR END STAGE RENAL DISEASE
5311	ACUTE GASTRIC ULCER WITH PERFORATION
5312	ACUTE GASTRIC ULCER WITH HEMORRHAGE AND PERFORATION
5315	CHRONIC OR UNSPECIFIED GASTRIC ULCER WITH PERFORATION
5316	CHRONIC OR UNSPECIFIED GASTRIC ULCER WITH HEMORRHAGE AND PERFORATION
5321	ACUTE DUODENAL ULCER WITH PERFORATION
5322	ACUTE DUODENAL ULCER WITH HEMORRHAGE AND PERFORATION
5325	CHRONIC OR UNSPECIFIED DUODENAL ULCER WITH PERFORATION
5326	CHRONIC OR UNSPECIFIED DUODENAL ULCER WITH HEMORRHAGE AND PERFORATION
5331	ACUTE PEPTIC ULCER OF UNSPECIFIED SITE WITH PERFORATION
5332	ACUTE PEPTIC ULCER OF UNSPECIFIED SITE WITH HEMORRHAGE AND PERFORATION
5335	CHRONIC OR UNSPECIFIED PEPTIC ULCER OF UNSPECIFIED SITE WITH PERFORATION
5336	CHRONIC OR UNSPECIFIED PEPTIC ULCER OF UNSPECIFIED SITE WITH HEMORRHAGE AND PERFORATION
5341	ACUTE GASTROJEJUNAL ULCER WITH PERFORATION
5342	ACUTE GASTROJEJUNAL ULCER WITH HEMORRHAGE AND PERFORATION

Step 4 (diagnosis of ESRD, CKD, pancreatitis, or severe GI disease)	
Required diagnosis: 1	
Look back timeframe: 730 days	
ICD-9 Code	Description
5345	CHRONIC OR UNSPECIFIED GASTROJEJUNAL ULCER WITH PERFORATION
5346	CHRONIC OR UNSPECIFIED GASTROJEJUNAL ULCER WITH HEMORRHAGE AND PERFORATION
5363	GASTROPARESIS
5372	CHRONIC DUODENAL ILEUS
555	REGIONAL ENTERITIS
5550	REG ENTERITIS, SM INTEST
5551	REG ENTERITIS, LG INTEST
5552	REG ENTERIT SM/LG INTEST
5559	REGIONAL ENTERITIS NOS
556	ULCERATIVE ENTEROCOLITIS
5560	ULCERATIVE ENTEROCOLITIS
5561	ULCERATIVE ILEOCOLITIS
5562	ULCERATIVE PROCTITIS
5563	ULCERATIVE PRCTOSIGMOIDITIS
5564	PSEUDOPOLYPOSIS COLON
5565	LFTSDED ULCERATIVE COLITIS
5566	UNIVRSL ULCERATIVE COLITIS
5568	OTHER ULCERATIVE COLITIS
5569	ULCERATIVE COLITIS UNSPCF
5589	NONINF GASTROENTERIT NEC
560	INTESTINAL OBSTRUCTION WITHOUT MENTION OF HERNIA
5600	INTUSSUSCEPTION
5601	PARALYTIC ILEUS
5602	VOLVULUS OF INTESTINE
56031	GALLSTONE ILEUS
5608	OTHER SPECIFIED INTESTINAL OBSTRUCTION
56081	INTESTINAL ADHES W OBSTR
56089	INTESTINAL OBSTRUCT NEC
5609	INTESTINAL OBSTRUCT NOS
56983	PERFORATION OF INTESTINE
577	DISEASES OF PANCREAS
5770	ACUTE PANCREATITIS
5771	CHRONIC PANCREATITIS
5854	CHRONIC KIDNEY DISEASE, STAGE IV (SEVERE).
5855	CHRONIC KIDNEY DISEASE, STAGE V.

Step 4 (diagnosis of ESRD, CKD, pancreatitis, or severe GI disease)	
Required diagnosis: 1	
Look back timeframe: 730 days	
ICD-9 Code	Description
5856	END STAGE RENAL DISEASE.
V56	ENCOUNTER FOR DIALYSIS AND DIALYSIS CATHETER CARE
V560	RENAL DIALYSIS ENCOUNTER
V561	FT/ADJ XTRCORP DIAL CATH
V562	FIT/ADJ PERIT DIAL CATH
V563	ENCOUNTER FOR ADEQUACY TESTING FOR DIALYSIS
V5631	HEMODIALYSIS TESTING
V5632	PERITONEAL DIALYSIS TEST
V568	DIALYSIS ENCOUNTER, NEC

Step 5 (procedure for ESRD services)	
Required diagnosis: 1	
Look back timeframe: 730 days	
CPT Code	Description
90918	ESRD RELATED SERVICES, MONTH
90919	ESRD RELATED SERVICES, MONTH
90920	ESRD RELATED SERVICES, MONTH
90921	ESRD RELATED SERVICES, MONTH
90922	ESRD RELATED SERVICES, DAY
90923	ESRD RELATED SERVICES, DAY
90924	ESRD RELATED SERVICES, DAY
90925	ESRD RELATED SERVICES, DAY
90935	HEMODIALYSIS, ONE EVALUATION
90937	HEMODIALYSIS, REPEATED EVAL
90940	HEMODIALYSIS ACCESS STUDY
90941	HEMODIALYSIS, INITIAL OR ACUTE (EG, ACUTE RENAL FAILURE OR INTOXICAT; PAT OVER 40 KG
90942	HEMODIALYSIS, INITIAL OR ACUTE (EG, ACUTE RENAL FAILURE OR INTOXICAT: PAT 21-40 KG
90943	HEMODIAL, INITIAL OR ACUTE (EG, ACUTE RENAL FAILURE OR INTOXICAT; PAT OVER 40 KG
90944	HEMODIAL, INITIAL OR ACUTE (EG, ACUTE RENAL FAILURE OR INTOXICAT; PAT UNDER 10 KG
90945	DIALYSIS, ONE EVALUATION
90947	DIALYSIS, REPEATED EVAL
90951	ESRD SERV, 4 VISITS P MO, <2

Step 5 (procedure for ESRD services)	
Required diagnosis: 1	
Look back timeframe: 730 days	
CPT Code	Description
90952	ESRD SERV, 2-3 VSTS P MO, <2
90953	ESRD SERV, 1 VISIT P MO, <2
90954	ESRD SERV, 4 VSTS P MO, 2-11
90955	ESRD SRV 2-3 VSTS P MO, 2-11
90956	ESRD SRV, 1 VISIT P MO, 2-11
90957	ESRD SRV, 4 VSTS P MO, 12-19
90958	ESRD SRV 2-3 VSTS P MO 12-19
90959	ESRD SERV, 1 VST P MO, 12-19
90960	ESRD SRV, 4 VISITS P MO, 20+
90961	ESRD SRV, 2-3 VSTS P MO, 20+
90962	ESRD SERV, 1 VISIT P MO, 20+
90963	ESRD HOME PT, SERV P MO, <2
90964	ESRD HOME PT SERV P MO, 2-11
90965	ESRD HOME PT SERV P MO 12-19
90966	ESRD HOME PT, SERV P MO, 20+
90967	ESRD HOME PT SERV P DAY, <2
90968	ESRD HOME PT SRV P DAY, 2-11
90969	ESRD HOME PT SRV P DAY 12-19
90970	ESRD HOME PT SERV P DAY, 20+
90976	PERITONEAL DIALYSIS FOR CHRONIC RENAL FAILURE; PATIENT MORE THAN 40 KG
90977	PERITONEAL DIALYSIS FOR CHRONIC RENAL FAILURE; PATIENT 21-40 KG
90978	PERITONEAL DIALYSIS FOR CHRONIC RENAL FAILURE; PATIENT 11-20 KG
90979	PERITONEAL DIALYSIS FOR CHRONIC RENAL FAILURE; PATIENT UNDER 10 KG
90982	PERITONEAL DIALYSIS FOR (ESRD), MAINT STABI COND, HOSP/OTHER FACIL PER SET; MORE 40 KG
90983	PERITONEAL DIALYSIS FOR (ESRD),MAINT STABL COND,HOSP/OTHER FAC PER SET;PATIENT 21-40 KG
90984	PERITONEAL DIALYSIS FOR (ESRD),MAINT STABI COND, HOSP/OTHER FAC PER SET;PATIENT 11-20 KG
90985	PERITONEAL DIALYSIS FOR (ESRD),MAINT STABI COND,HOSP/OTHER FAC PER SET;PATIENT UNDER 10K
90989	DIALYSIS TRAINING, COMPLETE
90990	HEMODIALYSIS TRAINING AND/OR COUNSELING
90991	HOME HEMODIALYSIS CARE, OUTPAT, SERV PROVID BY PHYSI RESPON FOR TOTAL CARE

Step 5 (procedure for ESRD services)	
Required diagnosis: 1	
Look back timeframe: 730 days	
CPT Code	Description
90992	PERITONEAL DIALYSIS TRAINING AND/OR COUNSELING (MEDICARE ONLY)
90993	DIALYSIS TRAINING, INCOMPL
90994	SUPERVISION OF CHRONIC AMBPERITONEAL DIAL (CAPD),HOME/OUT-PATIENT,MONTHLY

Step 6 (procedure for HbA1c test)	
Required procedure: 1	
Look back timeframe: 180 days	
CPT Code	Description
83036	GLYCOSYLATED HEMOGLOBIN TEST
83037	GLYCOSYLATED HB, HOME DEVICE

Step 8 (history of exenatide (Byetta))	
Required quantity: 1	
Look back timeframe: 365 days	
Label Name	GCN
BYETTA 5 MCG DOSE PEN INJ	24613
BYETTA 10 MCG DOSE PEN INJ	24614



Byetta (Exenatide Injection)

Clinical Edit Criteria References

1. Byetta™ [package insert]. San Diego, CA: Amylin Pharmaceuticals, Inc.
Available at <http://pi.lilly.com/us/byetta-pi.pdf>. Accessed on October 25, 2005.

Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

Publication Date	Notes
01/31/2011	Initial publication and posting to website
03/05/2012	<ul style="list-style-type: none">• Added a new section to specify the drugs requiring prior authorization• In the "Clinical Edit Criteria Supporting Tables" section, revised tables to specify the diagnosis codes pertinent to steps 2 and 4 of the logic diagram• In the "Clinical Edit Criteria Supporting Tables" section, revised tables to specify the drug names and GCNs pertinent to steps 3 and 8 of the logic diagram• In the "Clinical Edit Criteria Supporting Tables" section, revised tables to specify the procedure codes pertinent to steps 5 and 6 of the logic diagram