Clinical Edit Criteria Proposal

Drug/Drug Class: Relistor® Injection Clinical Edit
Date: June 25, 2013
Prepared for:
Prepared by: MO HealthNet

☒ **New Criteria** ☐ **Revision of Existing Criteria**

Executive Summary

Purpose: Ensure appropriate utilization and control of Relistor© (methylnaltrexone bromide subcutaneous injection).

Why was this Issue Selected: Relistor® is a branded drug product containing methylnaltrexone bromide used by subcutaneous injection for the treatment of constipation caused by opioids. Relistor® is indicated for opioid-induced constipation in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. Methylnaltrexone bromide is a selective anatagonist of the mu-opioid receptor, with limited ability to cross the blood brain barrier. This allows Relistor® to function as a peripherally-acting antagonist in tissues such as the gastrointestinal tract, thereby decreasing the constipating effects of opioids without impacting the analgesic effects on the central nervous system.

Program-specific information:

Drug	Dosage Form	Cost per Dosage Form
• Relistor®	*12mg Kit*	*$49.22/Kit WAC*
• Relistor®	*8mg PFS Kit*	*$123.05/ml WAC*
• Relistor®	12mg PFS Kit	*$82.03/ml WAC*
• Relistor®	12mg Vial	*$820.3/ml WAC*

Setting & Population: Patients ages 18 years or greater.

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Type of Criteria:	☐ **Increased risk of ADE** ☒ **Appropriate Indications**	☒ **Non-Preferred Agent** ☐
Data Sources:	☒ **Only administrative databases**	☐ **Databases + Prescriber-supplied**

Setting & Population

- Drug for review: Relistor® (methlynaltrexone bromide injection)
- Age range: Patients ages 18 years or greater.
- Gender: Male and female

Approval Criteria

- Patient is currently on opioid therapy (see Appendix C)
  - 90 out of 120 days
- Appropriate diagnosis (see Appendix B)
  - Constipation (ICD9 Code 564.0X) in past 180 days
- Appropriate age of patient
  - 18 years of age or older
- Trial and Failure of 2 appropriate laxative agents in last year
  - (see Appendix D)
- Contraindication to covered laxative products

Denial Criteria

- Failure to meet approval criteria.

References

1. Facts and Comparisons, p.382a – 382b. 2012.
2. USPDI, Micromedex, 2012.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2012.

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Appendix A

GCNs used to identify claim for Relistor® (methylnaltrexone bromide-subcutaneous injection)

GCN	GCN DESCRIPTION
99719	METHYLNALTREXONE BROMIDE 12MG/0.6ML KIT SUB-Q
31278	METHYLNALTREXONE BROMIDE 12MG/0.6ML DISP SYRIN SUB-Q
99722	METHYLNALTREXONE BROMIDE 12MG/0.6ML VIAL SUB-Q
31279	METHYLNALTREXONE BROMIDE 8 MG/0.4ML DISP SYRIN SUB-Q

Appendix B

Diagnosis codes used to identify positive history of constipation in the last 180 days

ICD-9-CM diagnosis	Code Description	ICD-10-CM diagnosis	Code Description
564.00	Constipation, unspecified	K59.00	Constipation, unspecified
564.01	Slow transit constipation	K59.01	Slow transit constipation
564.02	Outlet dysfunction constipation	K59.02	Outlet dysfunction constipation
564.09	Other constipation	K59.09	Other constipation

Appendix D

GCNs used to identify positive history of 2 laxative agents in the last year

Drug Name	GCN
FIBERCON 625 MG CAPLET	08342
KAOPECTATE 240 MG SOFTGEL	09061
EX-LAX CHOCOLATE	12162
EX-LAX MILK OF MAGNESIA SUS	07950
LAXATIVE TABLET	08762
STOOL SOFTENER 100 MG CAPSULE	09101
MINERAL OIL	09020
DOCUSATE SOD 20 MG/5 ML SYRUP	09152
SENNA-GEN NF TABLET	00701
SENNA S TABLET	13483
KONSYL POWDER	09440
KONSYL PACKET	09470
MINERAL OIL LIGHT	36940
DOCUSATE SODIUM 250 MG CAPSULE	09102
SENEXON 8.8 MG/5 ML LIQUID	08660
BISACODYL 10 MG SUPPOSITORY	08731
CASTOR OIL	08940
SM EPSOM SALT GRANULES	09200
SM ORAL SALINE LAXATIVE LIQUID	66560
PHILLIPS' MILK OF MAG (CONC)	07951
DOCUSATE SODIUM 100 MG TABLET	09171
EQUALACTIN 500 MG TAB CHEW	08351

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Drug Name	GCN
COLACE 50 MG CAPSULE	09105
DULCOLAX BOWEL PREP KIT	08770
EX-LAX ULTRA PILLS	00295
BENEFIBER POWDER	13478
BENEFIBER POWDER	13477
BENEFIBER CHEWABLE TABLET	22922
DOCUSATE SODIUM 50 MG/5 ML LIQ	09131
FLEET PREP KIT #3	65695
FLEET ENEMA	66559
FLEET MINERAL OIL ENEMA	09049
FLEET BISACODYL 10 MG ENEMA	08734
KONSYL-D POWDER	66600
KONSYL-D PACKET	67731
KONSYL-ORANGE POWDER	66610
KONSYL PACKET	67700
MAGNESIUM CITRATE SOLUTION	09240
CASTOR OIL	08930
K-PHOS #2 TABLET	03600
K-PHOS M.F. TABLET	03601
LO-SO PREP KIT	66670
SM CASTOR OIL	08942
OAT BRAN 500 MG TABLET	09531
METAMUCIL POWDER	55130
OAT BRAN 500 MG TABLET CHEW	09540
DOCUSOL MINI-ENEMA	10430
MURI-LUBE MINERAL OIL VIAL	08990
MILK OF MAGNESIA CONCENTRATED	97592
EX-LAX PILLS	00704
BENEFIBER PLUS CALCIUM POWDER	25325
BENEFIBER SUGAR FREE POWDER	27149
BENEFIBER 3 GM CAPLET	24476
SENNA SYRUP	24148
REGULOID CAPSULE	19220
OAT BRAN 850 MG CHEW TABLET	09542
SM SENNA LAXATIVE 8.6 MG SFTGL	21796
NATURAL VEG LAXATIVE TABLET	50386
FIBER-STAT LAXATION LIQUID	25498
METAMUCIL FIBER WAFER	51800
METAMUCIL PLUS CALCIUM CAPSULE	25087
PV FIBER LAXATIVE POWDER	97055
DOCUSATE SODIUM POWDER	09110
MINERAL OIL LIGHT VISCOSITY	09010
CVS PHOSPHATE ORAL SALINE LAX	97247

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Drug Name	GCN
CVS SENNA-EXTRA TABLET	26397
BISACODYL POWDER	90057
VISICOL TABLET	97016
OSMOPREP TABLET	12429
FIBER THERAPY POWDER	19642
SENNA PROMPT CAPSULE	25282
LIQUAFIBER LIQUID	21611
EX-LAX MAX RELIEF PILLS	19235
FLEET PEDIA-LAX ENEMA	98276
CASTOR OIL	98542
NATURAL FIBER LAX POWDER	14356
SM FIBER POWDER	14444
METAMUCIL POWDER	14393
CVS FIBER TABLET CHEWABLE	26167
BENEFIBER PLUS CALCIUM TB CHEW	98651
QC NATURAL VEGETABLE POWDER	14567
BENEFIBER SUGAR FREE CHEW TAB	98716
KONSYL SUGAR FREE PACKET	85671
BENEFIBER DRINK MIX POWDER	14237
FIBER POWDER	14139
LIQUAFIBER PACKET	16267
FIBER FLOW LIQUID	16229
CLEAR 2 GO POWDER	16233
LIQUID FIBER FLOW	16234
CVF FIBER SUPPLEMENT POWDER	16235
HYFIBER WITH FOS LIQUID PACKET	21092
CVS NATURAL FIBER SUPPLEMENT	22544
FLEET PEDIA-LAX STRIPS	25973
FIBER CHOICE PLUS CALCIUM TAB	27435
FIBER CHOICE WEIGHT MNGMNT TAB	27436
CVS NATURAL FIBER SUPP POWDER	27533
ENEMEEZ PLUS MINI ENEMA	30915
FIBER CHOICE CHEWABLE TABLET	30732
BENEFIBER POWDER PACKET	28885
BLACK DRAUGHT SENNA LAXATIVE	27635
BLACK DRAUGHT 90 MG/15 ML SYR	27724
FLEET PEDIA-LAX TABLET CHEW	28165
BENEFIBER PLUS HEART HLTH POWD	28404
BENEFIBER PLUS CALCIUM	28412
METAMUCIL CLEAR & NATURAL POWD	28553
CASCARA SAGRADA 450 MG CAPSULE	08532
HALFLYTELY-BISACODYL BOWEL KIT	28866
METAMUCIL POWDER	29035

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Drug Name	GCN
SUPREP BOWEL PREP KIT	28997
BENEFIBER SUGAR FREE POWDER	29078
CVS EASY FIBER CHEWABLE TABLET	29162
BENEFIBER + CALCIUM SUGAR-FREE	29094
FIBER SELECT GUMMIES TAB CHEW	30214
BENEFIBER 1 GRAM ULTRA CAPLET	30284
CVS EASY FIBER STICK PACK	30399
CVS FIBER GUMMIES TABLET CHEW	30378
FLEET ENEMA EXTRA	30697
FLEET PEDIA-LAX STOOL SOFTENER	09158
FLEET PEDIA-LAX FIBER GUMMIES	30721
COLOX 750 MG CAPSULE	30742
SENNA LEAVES	31754
ENEMEEZ MINI ENEMA	30916
HYFIBER WITH FOS LIQUID	33225
NARCOSOFT CAPSULE	31815
PSYLLIUM SEED POWDER	32505
PREPOPIK POWDER PACKET	29144
CHILD'S FIBER SELECT GUMMIES	34035

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