

New Guidelines for Hepatitis C Screening Help Identify Adults At-Risk

Hepatitis is an inflammation of the liver, and is often referred to as “viral hepatitis” because it is caused by one of several viruses. In the United States, the most common types of viral hepatitis are Hepatitis A, Hepatitis B and Hepatitis C. Unlike Hepatitis A, Hepatitis B and C can become chronic, life-long infections. According to the Centers for Disease Control and Prevention (CDC), more than four million Americans are living with chronic Hepatitis B or chronic Hepatitis C, but most do not know they are infected. While Hepatitis A and B are vaccine-preventable, Hepatitis C is not. Over time, Hepatitis C infection can lead to cirrhosis of the liver, end-stage liver disease and liver cancer. In the United States, chronic Hepatitis C infection is a leading cause of liver disease and liver transplants. Each year, approximately 15,000 Americans die from complications associated with chronic Hepatitis C infection.

In 2013, the U.S. Preventive Services Task Force (USPSTF) issued a “B recommendation” on screening for Hepatitis C in adults. The USPSTF found that screening will likely identify people who are infected with the virus, and screening can detect the infection before it causes serious damage to a person’s liver. Screening is most beneficial for people at high risk for being infected with hepatitis C, and recommends a one-time screening of adults born between 1945 and 1965.

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2nd Quarter
2014

Cigna Pharmacy ManagementSM

As a Pharmacy Benefits Manager (PBM) within a health service company, we deliver full-strength value management through full benefit connectivity.



Cigna looks at the big picture – the fully connected view of our customer

We help make Hepatitis C (HCV) medications more affordable, keep customers adherent and optimize their personal and professional productivity, increasing the chance of customers achieving a cure of HCV. Our approach to assuring affordability of the new treatment and the best outcomes include:

- Review all Hepatitis C treatments, including Sovaldi, for appropriate use through prior authorization
- Continuously evaluate coverage criteria using the latest clinical evidence
- When approved, cover Sovaldi at a non-preferred brand level on Cigna’s drug list
- Engage in discussions with pharmaceutical manufacturers to improve pricing terms
- Limit the medication to a 30-day supply at all specialty and retail pharmacies to minimize waste
- Offer therapy support services to every customer undergoing Hepatitis C treatment, including support by Hepatitis C expert pharmacists through Cigna Specialty Pharmacy ServicesSM
- Serve as patient advocates for our customers by supporting them from the time they start therapy, all the way through treatment, to ensure a successful outcome

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Hepatitis C screening involves testing a blood sample to see if it contains antibodies that react specifically to the hepatitis C virus. This test is followed by a second test that determines the level of virus in the blood. When used together, these two tests accurately identify whether a person has hepatitis C infection. For some people, once hepatitis C infection is identified, it can be successfully treated with medicine. Not everyone who is infected with the hepatitis C virus needs immediate treatment. Many people without signs of liver damage can be monitored and treated only if the virus becomes active. The goal of treatment is to prevent long-term damage to the liver from the infection.

Cigna covers Hepatitis C screening as a preventive care service provided by the Patient Protection and Affordable Care Act (PPACA). These preventive care services include periodic well visits, routine immunizations and certain designated screenings for symptom-free or disease-free individuals, and also include designated services for individuals at increased risk for a particular disease. PPACA requires health plans to cover preventive care services with no patient cost-sharing, unless the plan qualifies under the grandfather provision or for an exemption. PPACA designated specific resources that identify the preventive services required for coverage by the act, including USPSTF "A and B recommendations." Cigna covers Hepatitis C screening for adults at high risk for infection and one-time screening for adults born between 1945 and 1965 (effective 6/1/14).

Source: Centers for Disease Control and Prevention Division of Viral Hepatitis, May 9, 2014, and U.S. Preventive Services Task Force, June 2013.



New Cholesterol Guidelines Make 13 Million More U.S. Adults Eligible for Statins

New guidelines for using statins to treat high cholesterol and prevent cardiovascular disease are projected to result in 12.8 million more U.S. adults taking the drugs, according to a research team led by Duke Medicine scientists. The findings for the first time quantify the impact of the American Heart Association's new guidelines, which were issued in November and generated both controversy and speculation about who should be prescribed statins.

According to an analysis of health data published in the *New England Journal of Medicine* on March 19, 2014, a team led by researchers at the Duke Clinical Research Institute (DCRI) found that most of the additional statin users under the new guidelines would be people over the age of 60.

The new guidelines expand the criteria for statin use to include people whose 10-year risk of developing cardiovascular disease, including stroke, is elevated based on a risk-assessment score.

The DCRI-led research team determined that the new guidelines could result in 49 percent of U.S. adults ages 40-75 being recommended for statin therapy, an increase from 38 percent. The increase is much more pronounced among adults free of cardiovascular disease who are over age 60, with 77 percent recommended for statin use under the new guidelines vs. 48 percent under the previous standards. This contrasts with a modest increase from 27 percent to 30 percent among U.S. adults between the ages of 40 and 60. Those most affected by the new recommendations are older men who are not on statins and do not have cardiovascular disease. Under the earlier guidelines, about 30.4 percent of this group of men between the ages of 60-75 were recommended for statin use. With the new guidelines, 87.4 percent of these men would be candidates for the therapy. Similarly for healthy women in this age group, those recommended for preventive statin use are projected to rise from 21.2 percent to 53.6 percent.

Overall, of the 12.8 million additional U.S. adults recommended for statin use under the new guidelines, 10.4 million are people who would be prescribed the drugs for preventive care. Of those preventive users, 8.3 million would be people over the age of 60. The analysis also projects that an estimated 1.6 million adults previously eligible for statins under the old guidelines would no longer be candidates under the new standards. This group included primarily younger adults with elevated cholesterol but low 10-year risk of cardiovascular disease.

Source: Duke Medicine. "New guidelines deem 13 million more Americans eligible for statins." *ScienceDaily*. *ScienceDaily*, 19 March 2014. <www.sciencedaily.com/releases/2014/03/140319195717.htm>. Michael J. Pencina et al. *Application of New Cholesterol Guidelines to a Population-Based Sample*. *New England Journal of Medicine*, 2014 DOI: 10.1056/NEJMoa1315665

Cigna Enters into Innovative Pharmaceutical Contract with AstraZeneca

Cigna entered into a first-of-its-kind contract with AstraZeneca to help ensure that customers are given an appropriate cholesterol-lowering medication based on their treatment needs. By examining integrated medical and pharmacy information in predictive risk modeling, Cigna can identify customers at a high risk for cardiovascular events based on certain clinical factors and can fill Crestor® without requiring prior authorization.

As an integrated health services company, Cigna is able to use both medical and pharmacy information in predictive risk modeling to appropriately assess a customer's overall health condition. This approach analyzes multiple clinical factors to identify customers most at risk for atherosclerotic cardiovascular disease (ASCVD) related to high cholesterol. When a doctor prescribes Crestor, customers identified as being at higher risk will no longer be subject to "Step Therapy" – where a generic alternative is tried first – and can have their prescriptions for Crestor filled immediately.

"This program facilitates access to prescription therapy for customers who are identified as high risk," said Jon Maesner Pharm.D., Cigna's chief pharmacy officer. "Specifically, for our customers who are enrolled in benefit plans that include prescription Step Therapy requirements, Crestor is subject to a generic first-step edit," Maesner explains. "In this program, customers will have access to Crestor without going through Step Therapy if they are at high risk of cardiovascular event defined by clinical factors in predictive risk modeling. Customers who meet a predetermined risk threshold will be exempt from the generic step edit."

"Our arrangement with Cigna is an evolutionary step in supporting patient health, and facilitating access to Crestor for high risk patients. Predictive risk modeling can be used to help support the right treatment for the right patient at the right time, and we are excited to be working with Cigna because they are the only insurance carrier or Pharmacy Benefit Manager we have seen who has offered this capability," says Philip de Vane, MD, Executive Director of US Medical Affairs, AstraZeneca.

"Cigna's mission is to help the people we serve improve their health, well-being, and sense of security, and using predictive risk modeling for our customers aligns incentives to drive affordability and improved outcomes. It is a more effective way to manage prescription drug costs for employers and customers by making it easier for higher-risk patients to obtain important medicines like Crestor more quickly while still using generics where they are a viable alternative," says Chris Hocevar, President of Cigna Pharmacy Management and Select Business. "It is exciting to break new ground with AstraZeneca because they share our commitment to patients."

Crestor is now available to Cigna customers as the preferred brand name statin, saving customers out-of-pocket costs. This preferred status applies to both those who are determined to be at higher risk and those at lower risk who are not getting enough cholesterol lowering from treatment with a generic statin.

Source: Cigna Press Release, June 2, 2014, and Formulary Watch, June 9, 2014, by Tracey Walker.

AstraZeneca 



doctor/patient therapy
maintained



time saved with less administrative
hassle



pricing agreement with AstraZeneca through patent
expiration to further help customers and clients
save long-term



Trends in the Cost of Medical Care for Non-Elderly Adults with Diabetes

Diabetes is a prevalent and growing public health issue. In the United States, between 2000 and 2010, the proportion of adults with diabetes increased from 6 percent to 9 percent, or to about 21 million people. Diabetes presents a major financial challenge for both the patient and the health care system. In 2007, the estimated medical costs associated with diabetes were \$116 billion, with average medical expenses 2.3 times higher for people with the disease compared to those without.

Despite an increase in the prevalence of the disease, over the past 10 years, patients with diabetes have experienced a decrease in costs associated with treatment. This decrease may be due to the shift from brand name drugs to generics, resulting in a decrease in out-of-pocket spending for prescription medications.

Researchers analyzed data collected annually from 2001 to 2009 by the Federal Agency for Healthcare Research and Quality. The sample included adults between the ages of 18 and 64 who reported a diabetes diagnosis. The researchers looked at trends in out-of-pocket spending and other medical costs. Key findings included:

- Average out-of-pocket spending for people with diabetes decreased, with out-of-pocket medical care cost at \$1,373 in the period 2007 to 2009 compared with \$1,624 in 2004 to 2006. Out-of-pocket health care spending did not decrease significantly for the general population during the study period.
- While out-of-pocket spending on prescription medications accounted for more than half of all out-of-pocket spending, it decreased sharply, from \$1,095 in the period 2001 to 2003 to \$763 in 2007 to 2009.
- Generic drugs accounted for 52.9 percent of all diabetes-related prescriptions in 2007 to 2009, up from 46.9 percent in 2005 to 2006. This increase in generic medications accounts for 83 percent of the decrease in out-of-pocket spending.
- Families that spend more than 10 percent of their income on health care decreased, from 23.9 percent in 2001 to 2003 to 18.6 percent in 2007 to 2009.
- There was a decrease in hospital stays or emergency room visits over the study period.
- Consistent with the increased affordability of prescription drugs, fewer people with diabetes reported problems gaining access to prescriptions in 2007 to 2009 compared with earlier years.

Source: *American Journal of Managed Care*, Feb. 2014 20(2);135–42, Peter Cunningham and Emily Carrier.



More competitive. More choices. More savings. Coming 1/1/15.*

Cigna Pharmacy Management's coordinated approach to pharmacy solutions connects people, information and benefit programs to drive meaningful change in how pharmacy benefits are delivered and used. Now, we offer more competitive pricing and additional options for coverage and access to more effectively control cost. This package, combined with the value of our integrated approach, gives our clients a pharmacy solution that offers improved savings, better health outcomes and increased satisfaction.

We are enhancing the Value Drug List to include more preferred brand medications, while preserving the savings. The list limits preferred brands to those with highest value and excludes medications that have over-the-counter alternatives (stomach acid and allergy). Drug list removals can be applied to limit the use of brand drugs to those with highest value. It lowers price-point and offers access to suitable therapeutic alternatives.

Three new network options are also available for maximum savings: 1. National Pharmacy Network excluding CVS, 2. National Pharmacy Network excluding Walgreens and 3. National Pharmacy Network excluding CVS and Walgreens.

** Some options are ONLY available for clients with 2000 employees/ASO/ERISA and are manually implemented which will affect the customer experience. Talk to your Cigna representative for more information.*

Tecfidera Effectively Treats Relapsing Forms of Multiple Sclerosis

Tecfidera is an oral therapy for relapsing forms of multiple sclerosis (MS), including relapsing-remitting multiple sclerosis (RRMS), the most common form of MS. Tecfidera is currently approved in the United States, the European Union, Canada and Australia.

New data conducted by Biogen Idec reinforce the efficacy of Tecfidera in a wide range of patients with RRMS, as well as support its favorable safety and tolerability profile. These data were presented at the 66th American Academy of Neurology (AAN) annual meeting in Philadelphia.

A new post-hoc analysis from the Phase 3 studies reinforce that Tecfidera can be effective in RRMS patients with high disease activity. In addition, new data from the Phase 4 study show that gastrointestinal (GI) events experienced by patients in the clinical practice setting were mostly mild to moderate and generally manageable, and significantly decreased in prevalence within the first two months of treatment.

“These new data further reinforce the benefits Tecfidera’s strong efficacy may bring to a wide range of people with relapsing forms of multiple sclerosis (MS),” said Alfred Sandrock, M.D., Ph.D., group senior vice president and chief medical officer at Biogen Idec. “In addition, as we gain even more real-world experience with the therapy, it is encouraging to see that its tolerability profile remains manageable and that GI symptoms are largely transient.”

Results show that at two years, Tecfidera taken twice daily (BID; n=45) significantly reduced annualized relapse rate by 60 percent ($p=0.0018$) and the proportion of patients who relapsed by 63 percent ($p=0.0030$).

Source: Biogen Idec, April 30, 2014.



In the Multiple Sclerosis class: Effective 6/1/2014, Cigna moved Tecfidera and Copaxone (40 mg), from non-preferred brand to preferred brand status. Copaxone (20 mg), Avonex and Rebif are already preferred brands. These changes were made within a holistic approach to optimize affordability, health improvement and human performance.

Frequent Heartburn Relief Now Available Over-the-Counter with New Nexium® 24HR

Pfizer Inc. announced the introduction of Nexium® 24HR, making the medication available over-the-counter (OTC) for the treatment of frequent heartburn in adults ages 18 years and older. Frequent heartburn is defined as experiencing heartburn two or more days a week. Heartburn affects more than 60 million men and women in the United States at least once a month, with 15 million Americans suffering from it daily.

Pfizer acquired exclusive global OTC rights to Nexium®, one of the largest selling prescription brands in the U.S., from AstraZeneca in August 2012. Nexium 24HR was approved by the Food and Drug Administration on March 28, and received three-year market exclusivity. The launch of Nexium 24HR makes Pfizer a leading player in all four of the largest OTC categories – pain management, dietary supplements, respiratory and, now, digestive.

Nexium 24HR is a proton pump inhibitor (PPI) and works differently than other OTC medications for heartburn such as antacids and histamine blockers. PPIs stop acid production at the source, by blocking the pumps that release acid into the stomach. PPIs are the only FDA-approved medications for over-the-counter treatment of frequent heartburn.

Nexium 24HR is to be used once a day (every 24 hours), every day for 14 days, and may take one to four days for full effect. The 14-day course can be repeated every four months. People should not take more than one capsule of Nexium 24HR a day, unless directed by a doctor.

Source: Pfizer Inc., May 27, 2014.





Top 25 Best-Selling Drugs of 2013

In 2013, the best-selling drugs had at least \$3 billion in annual sales, which is triple the \$1 billion benchmark that has long defined “blockbuster” treatments. The list ranks drugs based on sales or revenue reported by biopharma companies in press announcements, annual reports, investor materials and conference calls during 2013.

Rank	Drug Name Sponsor	Condition	2013 Sales	2012 Sales	% Change
25	Avonex (interferon beta-1a) <i>Biogen Idec</i>	Multiple Sclerosis	\$3.005 billion	\$2.913 billion	3.2%
24	NovoLog/NovoRapid (Insulin aspart [rDNA origin] injection) - <i>Novo Nordisk</i>	Diabetes	\$3.101 billion	\$2.888 billion	7.4%
23	Truvada (emtricitabine and tenofovir disoproxil fumarate) - <i>Gilead Sciences</i>	AIDS/HIV	\$3.135 billion	\$3.181 billion	-1.4%
22	Symbicort (budesonide & formoterol) <i>AstraZeneca</i>	Asthma & Respiratory	\$3.483 billion	\$3.194 billion	9.0%
21	Diovan (Valsartan) & Co-Diovan (Valsartan and hydrochlorothiazide) - <i>Novartis</i>	Cardiovascular	\$3.524 billion	\$4.417 billion	-20.2%
20	Atripla (efavirenz, emtricitabine & tenofovir) <i>Gilead Sciences & Bristol-Myers Squibb</i>	AIDS/HIV	\$3.648 billion	\$3.574 billion	2.1%
19	Nexium (esomeprazole) <i>AstraZeneca</i>	Heartburn/Ulcer	\$3.872 billion	\$3.944 billion	-1.8%
18	Prevnar <i>Pfizer</i>	Infections	\$3.974 billion	\$4.117 billion	-3.5%
17	Januvia (sitagliptin) <i>Merck & Co.</i>	Diabetes	\$4.004 billion	\$4.086 billion	-2.0%
16	Revlimid (lenalidomide) <i>Celgene</i>	Cancer	\$4.280 billion	\$3.767 billion	13.6%
15	Copaxone <i>Teva Pharmaceutical Industries</i>	Multiple Sclerosis	\$4.328 billion	\$3.996 billion	8.3%
14	Neulasta (pegfilgrastim) <i>Amgen</i>	Cancer	\$4.392 billion	\$4.092 billion	7.3%
13	Lyrica (pregabalin) <i>Pfizer</i>	Pain Relief & Inflammatory Disease, Seizure	\$4.595 billion	\$4.158 billion	10.5%
12	Gleevec (also: Glivec, imatinib mesylate) <i>Novartis</i>	Cancer	\$4.693 billion	\$4.675 billion	0.4%
11	Cymbalta (duloxetine) <i>Eli Lilly and Shionogi</i>	Depression	\$5.191 billion	\$5.082 billion	2.1%
10	Abilify (aripiprazole) <i>Otsuka Pharmaceutical & Bristol-Myers Squibb</i>	Schizophrenia	\$5.265 billion	\$4.088 billion	28.8%
9	Crestor (rosuvastatin calcium) <i>AstraZeneca and Shionogi</i>	Cholesterol Lowering	\$5.994 billion	\$6.618 billion	-9.4%
8	Herceptin (trastuzumab) <i>Roche</i>	Cancer	\$6.839 billion	\$6.624 billion	3.1%
7	Avastin (bevacizumab) <i>Roche</i>	Cancer	\$7.037 billion	\$6.485 billion	8.5%
6	Lantus (insulin glargine) <i>Sanofi</i>	Diabetes	\$7.849 billion	\$6.648 billion	15.2%
5	Enbrel (etanercept) <i>Amgen and Pfizer</i>	Pain Relief & Inflammatory Disease, Skin Conditions	\$8.325 billion	\$7.963 billion	4.5%
4	Advair (fluticasone & salmeterol; Seretide) <i>GlaxoSmithKline</i>	Asthma & Respiratory	\$8.783 billion	\$8.402 billion	4.5%
3	Rituxan (rituximab, MabThera) <i>Roche (Genentech) & Biogen Idec</i>	Cancer	\$8.920 billion	\$8.646 billion	3.2%
2	Remicade (infliximab) <i>Johnson & Johnson and Merck & Co.</i>	Gastrointestinal (not heartburn/ulcer), Pain Relief & Inflammatory Disease, Skin Conditions	\$8.944 billion	\$8.215 billion	8.9%
1	Humira (adalimumab) <i>AbbVie</i>	Gastrointestinal (not heartburn/ulcer), Pain Relief & Inflammatory Disease, Skin Conditions	\$10.659 billion	\$9.265 billion	15.0%

Source: Genetic Engineering & Biotechnology News, March 3, 2014.



New Generic Releases - 2014 YTD

Generic Name	Former Brand Name	Common Use	U.S. Annual Sales Est.
Diclofenac topical	Pennsaid	Osteoarthritis	\$124M
Eszopiclone	Lunesta	Insomnia	\$851M
Hydromorphone	Exalgo	Pain	\$146M
Lomedia 24	Loestrin 24 FE	Oral contraceptive	\$396M
Sevelamer	Renvela	Kidney disease	\$200M
Sirolimus	Rapamune	Immunosuppressant	\$231M
Telmisartan	Micardis	Hypertension	\$249M
Telmisartan/hctz	Micardis HCT	Hypertension	\$218M
Tolterodine	Detrol LA	Overactive bladder	\$600M

Recent Drug Approvals

Brand Name	Common Use	FDA Approval Date
Impavido	Leishmaniasis	3/19/2014
Otezla	Psoriatic Arthritis	3/21/2014
Alprolix	Hemophilia B	3/28/2014
Oralair	Allergy immunotherapy	4/1/2014
Evzio	Opioid overdose	4/3/2014
Grastek	Allergy immunotherapy	4/11/2014
Tanzeum	Type 2 Diabetes	4/15/2014
Ragwitek	Allergy immunotherapy	4/17/2014
Cyramza	Gastric cancer	4/21/2014
Sylvant	Castleman's Disease	4/22/2014
Zykadia	Non-small cell lung cancer	4/29/2014
Incruse Ellipta	COPD	4/30/2014
Empanova	Triglycerides	5/5/2014
Zontivity	Anti-platelet	5/8/2014
Gel-Syn	Osteoarthritis of the knee	5/9/2014
Entyvio	Ulcerative Colitis	5/19/2014
Dalvance	Skin infections	5/23/2014



On the Horizon - Upcoming Patent Expirations

Target Date	Brand Name	Generic Name	Common Use	U.S. Annual Sales Est.
2Q 2014	Actonel	Risedronate	Osteoporosis	\$1.03B
2Q 2014	Copaxone	Glatiramer	Multiple Sclerosis	\$2.95B
3Q 2014	Lumigan	Bimatoprost	Glaucoma	\$367M
3Q 2014	Renagel	Sevelamer	Kidney disease	\$199M
4Q 2014	Exforge	Amlodipine/valsartan	Hypertension	\$263M
4Q 2014	Exforge HCT	Amlodipine/valsartan/Hctz	Hypertension	\$93M
4Q 2014	Intuniv	Guanfacine ER	ADHD	\$475M
4Q 2014	Celebrex	Celecoxib	Arthritis pain	\$1.75B
1Q 2015	Namenda	Memantine	Alzheimer's Disease	\$1.2B
1Q 2015	Tarka	Trandolapril/verapamil	Hypertension	\$29M
1Q 2015	Welchol	Colesevelam	Diabetes/Lipids	\$385M
2Q 2015	Abilify	Aripiprazole	Behavioral health	\$3.9B
2Q 2015	Emend	Aprepitant	Anti-emetic	\$114M
2Q 2015	Zyvox	Linezolid	Anti-infective	\$575M
2Q 2015	EpiPen	Epinephrine	Anaphylaxis	\$300M
3Q 2015	Aggrenox	Aspirin/dipyridamole	Stroke prevention	\$331M
4Q 2015	Avodart	Dutasteride	BPH	\$580M
4Q 2015	Jalyn	Dutasteride/tamsulosin	BPH	\$41M
4Q 2015	Frova	frovatriptan	Migraine headache	\$68M
4Q 2015	Patanol	Olopatadine	Allergic conjunctivitis	\$230M
4Q 2015	Ortho Tri-Cyclen Lo	Ethinyl estradiol/norgestimate	Oral contraceptive	\$424M
1Q 2016	Gleevec	Imatinib	Leukemia	\$1.45B
1Q 2016	Enablex	Darifenacin	Overactive bladder	\$268M
1Q 2016	Epzicom	Lamivudine/abacavir	HIV	\$375M
1Q 2016	Trizivir	Lamivudine/abacavir/zidovudine	HIV	\$112M
2Q 2016	Crestor	Rosuvastatin	Hyperlipidemia	\$6.6B
2Q 2016	Nuvigil	Armodafinil	Excessive daytime sleepiness	\$266M
3Q 2016	Ziana	Clindamycin/tretinoin	Acne	\$149M
3Q 2016	Advair Diskus	Fluticasone/salmeterol	Asthma/COPD	\$8B
4Q 2016	Benicar	Olmesartan	Hypertension	\$699M
4Q 2016	Benicar HCT	Olmesartan/HCT	Hypertension	\$605M
4Q 2016	Azor	Olmesartan/amlodipine	Hypertension	\$245M
4Q 2016	Seroquel XR	Quetiapine ER	Behavioral health	\$779M
4Q 2016	Zetia	Ezetimibe	Hyperlipidemia	\$1.9B
4Q 2016	Relpax	Eletriptan	Migraine headache	\$201M

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