100 Parsons Pond Drive, E2-2 Franklin Lakes, NJ 07417-2603

\ PHY \\00500224677\\00001797636\\\1150\\73\\00000000000\\07192012\\

30069 1 MB 0.404

MARY PHYSICIAN 123 MAIN STREET ANYTOWN, USA 11111-2222

00000686 120 30069

July 2012

Dear Dr. PHYSICIAN:

Express Scripts works with Company ABC to provide you with the enclosed RationalMed® safety and health considerations for patients in your practice.*

These records:

- Highlight safety and health considerations
- Provide prescription and medical claims information
- Cite relevant references

The claims information may include treatment provided by other healthcare providers.

Please review the health information provided and make any changes in therapy that you believe are appropriate. These records include available information related to the safety and health considerations, and may not represent your patient's complete medical or pharmacy history.

We understand that these considerations may not be applicable to every patient's therapy. We welcome your comments on how we may provide better support in your care of these patients. If you have any questions or comments, contact us at **1 800 xxx-xxxx** anytime between 8:00 AM and 8:00 PM (EST) Monday-Friday, and reference the patient-specific Control Number(s). Your feedback is kept confidential.

Thank you for your time and attention.

Peter F. Hoffman, M.D., PhD

Medical Director, Personal Health Solutions

*You were identified as a prescriber of record by a pharmacy dispensing medication for the patient listed. (See profile enclosed.)

Confidential Patient Information Safety and Health Considerations:

JANE PATIENT (50-123456789)

1. Drug Safety Consideration:METHYLPHENIDATE ER and SIGNIFICANT CARDIAC ABNORMALITY

50-123456789 XXXX DFSH.014 MED076 PCPFJP 00000686 / 00001828



Patient Name PATIENT, JANE

Date of Birth 01/01/2001 Control Number 50-123456789

(Please refer to this patient-specific Control Number when corresponding with Express Scripts.)

Requested Actions:

- Review the enclosed safety and health considerations.
- Review the information provided in the claims history.
- ✓ Make any warranted changes in therapy.

Considerations for Your Review

1. Drug Safety Consideration: METHYLPHENIDATE ER and SIGNIFICANT CARDIAC ABNORMALITY

Our claims record suggests that your pediatric patient is receiving METHYLPHENIDATE ER and may have a SIGNIFICANT CARDIAC ABNORMALITY. Sudden death has been reported in association with the use of stimulants or atomoxetine at usual doses in youth with structural cardiac abnormalities or other serious heart problems. Although studies in children and younger adults have not confirmed an increased risk of adverse cardiovascular events with ADHD drugs, atomoxetine, amphetamines and methylphenidate should generally not be used in children or adolescents with serious cardiac structural or rhythm abnormalities. Please consider the potential risks versus benefits of therapy for your patient. The American Heart Association advises physical exam, history and consideration of electrocardiogram if use of stimulants or atomoxetine is considered and pediatric cardiology referral if structural heart disease has been diagnosed.

Reference(s):

- US Food and Drug Administration. FDA Asks Attention-Deficit Hyperactivity Disorder (ADHD) Drug Manufacturers to Develop Patient Medication Guides. Updated July 1, 2009. http://www.fda.gov/DrugS/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm107918.htm
- 2. Vetter VL et al. American Heart Association Scientific Statement: Cardiovascular Monitoring of Children and Adolescents With Heart Disease Receiving Medications for Attention Deficit/Hyperactivity Disorder. Circulation. 2008;117:2407-23.
- American Heart Association. Top 10 Things To Know: Cardiovascular monitoring of children and adolescents with heart disease receiving stimulant drugs. Updated June 4, 2008. http://www.americanheart.org/downloadable/heart/1208873242075topTen_children.pdf
- 4. Perrin JM et al. Cardiovascular Monitoring and Stimulant Drugs for Attention-Deficit/Hyperactivity Disorder. Pediatrics. 2008;122(2):451-3.
- May DE & Kratochvil CJ. Attention-deficit hyperactivity disorder: recent advances in paediatric pharmacotherapy. Drugs. 2010;70(1):15-40.
- Schelleman H et al. Cardiovascular Events and Death in Children Exposed and Unexposed to ADHD Agents (published online May 16, 2011). Pediatrics. 2011. DOI:10.1542/peds.2010-3371
- US Food and Drug Administration. FDA Drug Safety Communication: Safety Review Update of Medications used to treat Attention-Deficit/Hyperactivity Disorder (ADHD) in children and young adults. Updated November 08, 2011. http://www.fda.gov/DrugS/DrugSafety/ucm277770.htm
- Shaw P. ADHD medications and cardiovascular risk: Some heartening news [published online December 12, 2011]. JAMA. 2011. DOI:10.1001/jama.2011.1866

(Over, please)



Patient Name **PATIENT, JANE**

Date of Birth 01/01/2001 Control Number 50-123456789

(Please refer to this patient-specific Control Number when corresponding with Express Scripts.)

Requested Actions:

- ✓ Review the enclosed safety and health considerations.
- ✓ Review the information provided in the claims history.
- ✓ Make any warranted changes in therapy.

Rx	P	ro	fil	ما
IVA	г.	ıv	ш	

Consideration	Date of Service	Drug Description	Strength	Qty	Days Supply	Prescriber	Pharmacy Name Phone Number
1	06 24 12	METHYLPHENIDATE ER	54 MG	30	30		MAIN STREET PHARMACY 800-xxx-xxxx
1	04 29 12	METHYLPHENIDATE ER	54 MG	30	30		MAIN STREET PHARMACY 800-xxx-xxxx

Medical History

	Date of		
Consideration	Service	Claim Type	Diagnosis / Procedure Description
1	04 03 12	OUT PATIENT	CONG TRICUSP ATRES/STEN
1	03 28 12	OUT PATIENT	CONG HEART ANOMALY NOS
1	02 10 12	OUT PATIENT	CONG TRICUSP ATRES/STEN
1	02 10 12	OUT PATIENT	CONG HEART ANOMALY NOS
1	02 10 12	OUT PATIENT	COMMON VENTRICLE
1	02 09 12	OUT PATIENT	CONG HEART ANOMALY NOS
1	02 09 12	OUT PATIENT	CONG TRICUSP ATRES/STEN
1	01 13 12	OUT PATIENT	CONG TRICUSP ATRES/STEN
1	08 22 11	OUT PATIENT	COMMON VENTRICLE
1	08 22 11	OUT PATIENT	CONG TRICUSP ATRES/STEN
1	07 15 11	OUT PATIENT	CONG TRICUSP ATRES/STEN

These records may not represent your patient's complete medical history. You were identified by a dispensing pharmacy as a "prescriber of record" for prescriptions filled under this patient's prescription drug benefit. If you were incorrectly identified as a "prescriber of record", please contact the dispensing pharmacy at the phone number provided.

Express Scripts understands that the health information may not be applicable to every patient's therapy and, therefore, presents it as informational only.

Thank you for your time and consideration. If you have any questions or comments, please call **1800** xxx-xxxx anytime between 8:00 AM and 8:00 PM (EST) Monday-Friday, and reference the patient-specific Control Number(s).