

Uses, Common Types, and Costs of Compounded
Bioidentical HRT Products

and

Patient Preferences Regarding Compounded BHRT
Products

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Our Research

1. Timothy McPherson, Patrick Fontane, Reethi Iyengar, Rochelle Henderson. Utilization and Costs of Compounded Medications for Commercially Insured Patients, 2012-2013.
Journal of Managed Care and Specialty Pharmacy 2016;22(2):172-81
2. Timothy McPherson, Patrick Fontane, Rhonda Bilger. Patient Experiences with Compounded Medications. Journal of the American Pharmacists Association, submitted
Supported by Focus Script LLC.

Compounded Products Are Used to Treat a Variety of Medical Conditions.

1. BHRT (50%)
2. Pain - topical creams (23%)
3. Thyroid disorders (6%)
4. Sinus/nasal conditions
5. Infections
6. Other
 - Dermatologic conditions
 - Migraine
 - Erectile dysfunction
 - Lupus
 - Gastrointestinal conditions

Characteristics of Female BHRT Users

- N=222
- Age 17 – 83, average 59 years
 - Approximately 80% of users between 50 – 70 years old
- Respondents represented 15 states
- 91% considered themselves to be in good or excellent health
- Average duration of use was 4 years
 - ~85% between 6 months – 10 years
 - 5 respondents reported 20 years or longer

A Minority of BHRT Users are Male

- 3.5% of BHRT users
- Testosterone replacement
- Duration of use ranged from 2 months – 6.5 years

Hormones Used in Compounded BHRT for Females

- Progesterone
- Estradiol
- Estriol
- Estrone
 - Bi-est (estradiol + estriol)
 - Tri-est (estradiol + estriol + estrone)
- Testosterone
- DHEA (dehydroepiandrosterone)
- Multiple combinations of 2, 3, 4, or 5 hormones within the same product

The Most Frequently Compounded Hormones for Female BHRT Patients

- Progesterone
 - Alone 59%
 - Combinations 15%
- Estradiol
 - Alone 18%
 - Bi-est 26%
 - Other combinations 26%
- Testosterone
 - Alone 26%
 - Combinations 26%
- Most BHRT patients reported using multiple hormones

Compounded Hormones Are Administered in a Variety of Dosage Forms

- Oral
 - Capsule
 - Sustained release capsule
 - Fast dissolve tablet
 - Sublingual lozenge or drops
- Transdermal
 - Proprietary bases
 - Versabase[®] line (PCCA), Pracasil-Plus[®] (PCCA), HRT Base Cream[®] (Medisca), Pentravan[®] (Fagron)
- Vaginal cream or suppository

Costs of Compounded BHRT

- Two types of cost data
 - Patient-reported out of pocket cost, irrespective of insurance coverage
 - Our 2017 patient survey data
 - Aggregate annual costs to insurers
 - Express Scripts database - JMCP 2016 paper
 - Large pharmacy benefit manager and mail order pharmacy
 - Data reflect patients with commercial insurance coverage (no worker's compensation, Medicare/Medicaid, or TriCare claims)
 - Not patient costs

Out of Pocket Cost Reported by Female BHRT Patients

- Costs are not normalized to days supply, nor separated by drug or dosage form. Results exclude 3 outliers over \$2,000.

Statistic	All Female BHRT	No insurance	Insured
Mean	\$88	\$91	\$71
Median	\$70	\$85	\$40
Mode	\$70	\$90	\$45
25 th %ile	\$49	\$52	\$23
75 th %ile	\$110	\$115	\$62
Number of responses	206	174	28

Average Out of Pocket Cost is Higher for Compounded BHRT Than Non-Compounded Prescriptions

Statistic	All Female BHRT	No insurance	Insured
Mean	\$88	\$91	\$71
Median	\$70	\$85	\$40

- Previous report average out of pocket cost for HRT: \$49
Pinkerton JV, Santoro N. Menopause 2015;22:926-936
- Average out of pocket cost for all prescriptions for insured patients in 2017: \$28
M Aitken. Medicine Use and Spending in the U.S. A Review of 2017 and outlook to 2022. <https://www.iqvia.com>
- Average cash price for a non-insured prescription in the US in 2017: \$68
Kaiser Family Foundation. Health costs and budgets - prescription drugs. <https://www.kff.org/>

Costs of Compounded BHRT from Insurance Claims Data

Demographics for 2013

<div>TABLE 1</div> Demographic Data			
	2012	2013	Change
Eligible members	22,314,101	22,745,508	431,407 (1.9%)
Prescription medication users	14,960,649	15,110,518	149,869 (1.0%)
Prevalence of prescription medication users (%)	67.0	66.4	-0.9
Average age, years (SD)	36.9 (20.7)	36.8 (20.6)	-0.1 yr
Female	11,508,347	11,713,474	1.8%
Percent female	51.6	51.5	-0.2
Compound users	245,285	323,501	78,216 (31.9%)
Prevalence of compound users (%)	1.1	1.4	27.3
Average age, years (SD)	41.8 (21.3)	42.3 (21.1)	0.5 yr
Female	162,471	212,590	30.8%
Percent female	66.2	65.7	-0.8

SD = standard deviation.

Bioidentical Hormones Were Among the 10 Most Frequently Compounded Ingredients in 2013

- Ranked by number of compounded claims the drug appeared in

Age Range	Female	Male
20 - 29	Progesterone (#6)	No BHRT
30 - 39	Progesterone (#6), Testosterone (#10)	Testosterone (#10)
40 - 49	Progesterone (#1), Testosterone (#5), Estradiol (#6)	Testosterone (#6)
50 - 59	Progesterone (#1), Estradiol (#2), Testosterone (#3), Estriol (#7)	Testosterone (#4)
60 - 69	Progesterone (#1), Estradiol (#2), Testosterone (#5), Estriol (#9)	Testosterone (#4)
≥70	Progesterone (#8), Testosterone (#10)	Testosterone (#6)

Despite High Frequency, Hormones Did Not Rank Highly in Most Expensive Compounded Ingredients in 2013

- Rank by total cost billed for the drug
 - Number of claims x ingredient cost

Age Range	Female	Male
20 - 29	No BHRT	No BHRT
30 – 39	No BHRT	Testosterone (#5)
40 - 49	Progesterone (#10)	Testosterone (#8)
50 - 59	Progesterone (#9)	Testosterone (#7)
60 - 69	Progesterone (#9)	Testosterone (#9)
≥70	No BHRT	Testosterone (#9)

Patient Preferences for Manufactured versus Compounded Prescriptions

- Three indicators of patient perceptions of BHRT
 - Satisfaction with the compounded product
 - Satisfaction with compounded as compared to previous products used for the same condition
 - Explanation of why they chose compounded product

Female BHRT Users Were Very Satisfied with Their Compounded Products

Indicate your level of satisfaction with:	Very Dissatisfied (%)	Somewhat Dissatisfied (%)	Somewhat Satisfied (%)	Very Satisfied (%)
Relief from the medical condition	0	1	19	80
Interaction with the pharmacy	0	1	14	85
Overall satisfaction	0	1	12	87
Out of pocket cost	21	31	34	14

n = 209 – 217 per item

Female BHRT Users Were More Satisfied with Compounded Products than Previous Medications

CRx = compounded product

How does the CRx compare to previous medications in terms of:	CRx Much Worse (%)	CRx Somewhat Worse (%)	CRx About the Same (%)	CRx Somewhat Better (%)	CRx Much Better (%)
Relief from the medical condition	1	2	7	8	81
Side effects	1	1	18	8	72
Interaction with the pharmacy	0	1	23	13	63
Out of pocket cost	40	29	13	7	11

n = 105 - 113 per item

Female BHRT Users Prefer Natural Hormones and Individualized Doses

- “Why did you and your physician decide to use this compounded medication?”
- 113 female BHRT users entered a free text response
- 39% preferred “bioidentical” or “natural” hormones
 - “Safer,” “fewer side effects,” “healthier option”
 - Do not like “synthetic” hormones
 - Representative comments
 - “All natural/bioidentical option; I do not want synthetic”
 - “Wanted to use a more natural product + safer”
- 14% preferred BHRT because the dose was individualized for them
- BHRT users reported wanting to receive care from professionals who listened to them and understood, and did not dismiss, their symptoms
Soc Sci Med 2015;132:79-87; BMC Womens Health 2017;17:97

Do you think use of compounded medications will increase, plateau, or decrease?

- Our data cannot address this question
 - Global Market Insights projects an increasing market for compounded medications in general through 2025.
 - Steady growth in compounded BHRT market is also predicted
- <https://www.gminsights.com/industry-analysis/us-compounding-pharmacies-market>

U.S. Compounding Pharmacies Market, By Therapeutic Area

U.S. Compounding Pharmacies Market, By Therapeutic Area, 2014 – 2025 (USD Billion)



Any Suggestions Regarding How Patient Preferences Should Be Weighed with Current Evidence of Effectiveness?

- We take no position on the safety or efficacy of BHRT
- Benefits of drug therapy
 - Objective clinical efficacy
 - Perceived symptom relief
 - Effect on quality of life
- BHRT users indicated that their products were beneficial and they were willing to pay prices with which they were dissatisfied

What specific recommendations (if any) would you like to see come from the committee's report?

- Standards for compounding practice are set forth in USP <795> *Pharmaceutical Compounding – Nonsterile Preparations*
 - General guidelines
- Consider recommending development of official USP monographs for common BHRT products
 - Validated formulations
 - Specific purity, potency, and stability criteria
 - USP Compounded Preparations monographs
 - Progesterone Compounded Vaginal Inserts USP
- Consider recommending a prioritized research agenda to answer questions that are not settled with available data
 - Patterns of compounded BHRT use by older women and longer term users (e.g. ≥ 5 years)
 - Use of compounded testosterone products by men

Thank You