ISSUE BRIEF

Out-of-Pocket Payments for the Fixed-Dose Combination of Hydralazine and Isosorbide Dinitrate (BiDil)

March 8, 2017

"The seeker after the truth is not one who studies the writings of the ancients and, following his natural disposition, puts his trust in them, but rather the one who suspects his faith in them and questions what he gathers from them, the one who submits to argument and demonstration, and not to the sayings of a human being whose nature is fraught with all kinds of imperfection and deficiency. Thus the duty of the man who investigates the writings of scientists, if learning the truth is his goal, is to make himself an enemy of all that he reads, and, applying his mind to the core and margins of its content, attack it from every side. He should also suspect himself as he performs his critical examination of it, so that he may avoid falling into either prejudice or leniency."

—*Ibn al-Haytham (Sabra AI, "Ibn al-Haytham: Brief life of an Arab mathematician: died circa 1040," Harvard Magazine, September–October 2003, http://harvardmagazine.com/2003/09/ibn-al-haytham-html)*

About the National Minority Quality Forum

The National Minority Quality Forum is a Washington, DC–based not-for-profit, nonpartisan, independent research and education organization dedicated to improving the quality of health care that is available for and provided to all populations. The Forum develops user-friendly, web-based indices that provide unique views of the prevalence and impact of diseases and other health indicators by zip code and other geographical areas. Our website is http://www.nmqf.org/. We are on Facebook (National Minority Quality Forum) and on Twitter (@NMQF, at http://www.twitter.com/NMQF).

In 2004, Taylor et al. reported results from the African-American Heart Failure Trial (A-HeFT), which evaluated hydralazine hydrochloride plus isosorbide dinitrate as a fixed-dose combination (F-H/ISDN) in black patients who had New York Heart Association class III or class IV heart failure (HF).[1] F-H/ISDN reduced all-cause mortality by 43% and first hospitalization by 39%, and it improved response to the Minnesota Living with Heart Failure questionnaire, a self-report of the patient's functional status.

In June 2005, the US Food and Drug Administration approved F-H/ISDN as a new drug for the treatment of HF in self-identified blacks. The 2013 American College of Cardiology Foundation/American Heart Association Guideline for the Management of Heart Failure recommends hydralazine and isosorbide dinitrate as adjunctive therapy for African Americans with HF who remain symptomatic despite concomitant use of angiotensin-converting-enzyme inhibitors, beta blockers, and aldosterone antagonists.[2] F-H/ISDN received a class 1 level A recommendation, indicating that the treatment should be performed.

Fonarow et al. have calculated that "a substantial number of HF deaths in this country could potentially be prevented by optimal implementation of evidence-based therapies."[3] Applying their calculation to African American Medicare beneficiaries living with HF, appropriate use of F-H/ISDN could have prevented 5,000 premature deaths annually. From 2005 through 2015, 85,000 black Medicare beneficiaries may have died prematurely because they did not receive the standard of care. We estimate that 97% of African American Medicare beneficiaries with HF

---

[1] Taylor AL, Ziesche S, Yancy C, Carson P, D'Agostino R Jr, Ferdinand K, Taylor M, Adams K, Sabolinski M, Worcel M, Cohn JN for the African-American Heart Failure Trial Investigators. Combination of isosorbide dinitrate and hydralazine in blacks with heart failure. N Engl J Med. 2004; 351(20):2049–2057 (http://www.nejm.org/doi/full/10.1056/NEJMoa042934, accessed 7 March 2017).

[2] Yancy CW, Jessup M, Bozkurt B, Butler J, Casey DE Jr, Drazner MH, Fonarow GC, Geraci SA, Horwich T, Januzzi JL, Johnson MR, Kasper EK, Levy WC, Masoudi FA, McBride PE, McMurray JJV, Mitchell JE, Peterson PN, Riegel B, Sam F, Stevenson LW, Tang WHW, Tsai EJ, Wilkoff BL. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013; 128(16):e240–e327, p. e270 (http://circ.ahajournals.org/content/128/16/e240, acessed 7 March 2017).

[3] Fonarow GC, Yancy CW, Hernandez AF, Peterson ED, Spertus JA, Heidenreich PA. Potential impact of optimal implementation of evidence-based heart failure therapies on mortality. Am Heart J. 2011; 161(6):1024–1030.e3, p. 1024 (http://www.ahjonline.com/article/S0002-8703(11)00206-7/abstract, accessed 7 March 2017).

eligible for F-H/ISDN are not receiving the medication, in spite of the class 1 level A recommendation for F-H/ISDN.

Concern exists that blacks cannot afford F-H/ISDN, and therefore physicians are reluctant to prescribe it.[4] The National Minority Quality Forum conducted a study to determine out-of-pocket payments made by African American Medicare beneficiaries who filled a prescription for the fixed dose combination (BiDil) in 2013.[5] Over 60% of African Americans with HF are Medicare beneficiaries, so out-of-pocket payments by these beneficiaries provide a useful index on what all African Americans with HF are paying out of pocket for the medication.

We obtained Medicare administrative data from the Centers for Medicare & Medicaid Services (CMS). This study used the Master Beneficiary Summary File: Base Segment, Chronic Conditions Segment, Cost and Utilization Segment for the year 2013 and the Medicare Part D event files. CMS compiles the Master Beneficiary Summary File annually; it contain demographics (e.g., date of birth/death, gender, race), enrollment (e.g., number of months enrolled in Part A), and 21 chronic conditions, one of which is HF, for all beneficiaries who were alive and enrolled in Medicare for any part of the year. CMS uses an algorithm that examines patterns of medical-care utilization, as determined by Medicare fee-for-service claims, to calculate each beneficiary's status for these chronic-condition fields. A yearly indicator (CHF) specifies that the beneficiary was treated for HF that year.

Medicare began offering a prescription-drug benefit in 2003 under Medicare Part D. Part D beneficiaries may be responsible for paying for a portion of medication costs, which is referred to as an out-of-pocket payment. The Medicare Part D Event File records transactions for prescription drugs that are reimbursed under Medicare Part D. This file includes a field (PTNT_PAY_AMOUNT) that captures the amount that a beneficiary pays out of pocket for a drug. The file also contains a field (BN) that provides a medication's brand name. Using the BN and PTNT_PAY_AMOUNT fields, we identified each transaction in which BiDil was prescribed and the associated out-of-pocket payment made by the beneficiary for the year 2013. Linking beneficiaries' unique identifiers in the Master Beneficiary Summary File with the Part D Event

[4] Dr. Mark Creager, President, American Heart Association/American Stroke Association; Submitted by Ms. Melanie Shahriary, RN, BSN, Comments Received and Actions Taken, December 2015, https://www.qualityforum.org/ProjectMaterials.aspx?projectID=77914.

[5] Center for Medicare and Medicaid Services, Medicare Part D Event File, 2013.

file, we found 8,945 claims for BiDil by African American beneficiaries with HF, which included the beneficiaries' out-of-pocket payments.

We used SAS software, version 9.3 to calculate a percentile distribution from the out-of-pocket payments that were associated with the 8,945 claims. In 2013 the median out-of-pocket payment per tablet by African American Medicare beneficiaries with HF was $0.06, and 25% of them had no out-of-pocket expenditure for the medication (Table 1). Optimal daily dosage is six tablets. Among African American beneficiaries with HF who were prescribed the optimal dosage, 50% were paying out of pocket $0.36 or less per day and 75% were paying $2.00 or less per day.

Table 1. Out-of-Pocket Payments for BiDil by African American Medicare Beneficiaries, 2013

	Out-of-Pocket Payment						
Payment Category	**Minimum**	**Max-imum**	**10th Percentile**	**Lower Quartile**	**Median**	**Upper Quartile**	**90th Percentile**
Per tablet	$0.00	$2.43	$0.00	$0.00	$0.06	$0.33	$0.70
Optimal dosage (6 tablets/day)	$0.00	$14.58	$0.00	$0.00	$0.36	$1.98	$4.20

The study demonstrates that out-of-pocket cost for Medicare beneficiaries is a function of formulary placement. Some plans' formularies allow African Americans to obtain the medication for free, whereas others require out-of-pocket payments of $4.20 or more per day. A majority of African American beneficiaries are in formularies where they pay as little as $.35 per day for the drug.

There is a need for a quality-improvement initiative to encourage physicians to treat blacks according to AHA/ACC guidelines. We hope that this study contributes to wider use of evidence-based care for blacks with HF.